UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

IN RE CARACO PHARMACEUTICAL LABORATORIES, LTD. SECURITIES LITIGATION	No. 2:09-CV-12830-AJT-DAS CLASS ACTION **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** DEMAND FOR JURY TRIAL

THE MILLER LAW FIRM, P.C.
E. Powell Miller (P39487)
Jayson E. Blake (P56128)
Christopher D. Kaye (P61918)
950 West University Drive, Suite 300
Rochester, Michigan 48307
Telephone: (248) 841-2200
Facsimile: (248) 652-2852

GLANCY BINKOW & GOLDBERG LLP
Lionel Z. Glancy
Peter A. Binkow
Michael Goldberg
1801 Avenue of the Stars, Suite 311
Los Angeles, California 90067
Telephone: (310) 201-9150
Facsimile: (310) 201-9160

Co-Lead Counsel for Plaintiffs

[Additional Counsel on Signature Page]

BODMAN LLP
Dennis J. Levasseur (P39778)
6th Floor at Ford Field
1901 St. Antoine Street
Detroit, Michigan 48226
Telephone: (313) 259-7777
Facsimile: (313) 393-7579
Email: dlevasseur@bodmanllp.com

BRIGGS AND MORGAN, P.A.
Frank A. Taylor
Margaret Adamczyk Goetze
2200 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402
Telephone: (612) 977-8663
Facsimile: (612) 977-8650
Email: ftaylor@briggs.com
Email: mgoetze@briggs.com

Counsel for Defendants Caraco Pharmaceutical Laboratories, Ltd. and Daniel H. Movens

TABLE OF CONTENTS

Lead Plaintiff Tushar Amin ("Lead Plaintiff"), Plaintiff Kevin Koziatek, and Plaintiff Jonathan Wilkof (collectively "Plaintiffs"), by and through their attorneys ("Co-Lead Counsel"), allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Caraco Pharmaceutical Laboratories, Ltd. ("Caraco" or the "Company") with the United States Securities and Exchange Commission ("SEC") and by Sun Pharmaceutical Industries, Ltd. ("Sun Pharma" or "Sun Pharmaceutical"); (b) review and analysis of press releases and media reports issued by and disseminated by Caraco and Sun Pharma; (c) review of other publicly available information concerning Caraco and Sun Pharma; and (d) review and analysis of information concerning the Company on file at the United States Food and Drug Administration (the "FDA").

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a federal class action on behalf of purchasers of Caraco's securities between May 29, 2008 and June 25, 2009, inclusive (the "Class Period"), seeking remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Defendant Caraco primarily develops, manufactures, markets and distributes generic and private-label pharmaceuticals to wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers throughout the U.S and Puerto Rico. These pharmaceuticals treat a variety of chronic disorders including but not limited to the following: hypertension, arthritis, epilepsy, diabetes, psychosis, depression and chronic pain. Although generic drug production is a crowded field, the company which is the first to

successfully file an Abbreviated New Drug Application ("ANDA") with the FDA can, once exclusive sales right for branded drugs expires, itself enjoy a 180-day sales exclusivity period.

3. Caraco's 76% majority owner is Sun Pharma, an international pharmaceutical company headquartered in India. With Sun Pharma's financial and research and development support, the latter including five-year technology transfer agreements in 1997 and 2002, Caraco has been able to submit several dozen applications to the FDA to be approved to manufacture and sell generic formulations for some of the most widely-purchased drugs on the market. In addition, Caraco entered into agreements with Sun Pharma to act as a distributor of Sun Pharma's products. With Sun Pharma's backing, Caraco had begun to compete with much larger companies in the highly-competitive generic drug market. In fact, between fiscal 2007 (which ended March 31, 2007) and fiscal 2008, Caraco's sales volume tripled, from $117 million to $350 million.

4. With these breath-taking results, from an investor's perspective, although Caraco was a small cap company at the beginning of the Class Period, with its numerous applications then pending before the FDA, Caraco thus had enormous growth potential as Sun Pharma's primary presence in the lucrative United States market. What Class Period investors were not told was that Caraco did not have the capacity to handle the level of growth it aspired to by attempting to manufacture and sell almost every product Sun Pharma offered it under its various agreements.

5. Defendants, including the Company's Chief Executive Officer ("CEO") Daniel H. Movens ("Movens"), already a 25-year industry veteran when he was selected to lead Caraco in April 2005, were well aware that the FDA would inspect Caraco's facilities, *inter alia*, in

connection with the approval process for then-pending applications. Thus, it was imperative that the Company's manufacturing and packaging facilities be in compliance with the FDA's current Good Manufacturing Practices ("cGMP") regulations. If not, the FDA could delay approval and another company could possibly obtain the 180-day exclusivity on its ANDA. Much worse, if serious problems existed – and persisted – with respect to drugs already being manufactured, the FDA could determine that the drugs were "adulterated" (as that term is defined in the Food Drug and Cosmetic Act) and cease all production and distribution.

6. During CEO Movens's tenure, between 2005 and 2008, the Company had been informed about defective and deficient conditions by the FDA following several inspections, *via* the issuance of FDA Form 483, an inspection report which is issued to senior management upon the conclusion of an on-site inspection. While the Company acknowledged the receipt of such notices of infractions, in its public filings with the SEC, Caraco minimized both their scope and their overall significance.

7. Quite the contrary was true. Accounts from ten confidential witnesses[1] who were employed by Caraco during all or part of the Class Period explained that appalling conditions existed in the company's Detroit facility, conditions which imperiled the lives of consumers of Caraco's products, including, but not limited to: failures to account for missing inventory – including, in one instance, of Digoxin, a Class 2 drug that could be lethal at the wrong dosage; the repeated manufacture of pills that were too thin, too thick or were not of the proper weight for dosing purposes; the use of machinery designed to make small quantities of vitamins for Caraco's production of large quantities of high-grade pharmaceutical products; repeated

[1] Each confidential witness ("CW") is described in detail in Section VII below.

instances of hair contamination; ever-changing and insufficient Standard Operating Procedures; and delayed submission of customer complaints to the FDA. One witness likened Caraco's activities to "the Wild West"; another, who was "amazed" at how the Company was operating, once commented to the Manufacturing Vice President that if the FDA saw what was happening, the agency would shut down the Company. And while Defendant Movens, in rationalizing the Company's improper use of shoddy compression machines, likened the machinery the Company was using as an acceptable "Buick" rather than a "Cadillac," one confidential witness likened the machines to a "Yugo" instead. The haunting stories of the various witnesses all confirm that the Company's operations were not experiencing isolated problems, but long-term and persistent failures to produce unadulterated drugs at any acceptable level.

8. Just as it had prior to the Class Period, Caraco's public statements during the Class Period all indicated that the Company was doing its best to ensure the production of top quality products. As set forth in detail below, whenever the Company did discuss problems it encountered with the FDA, it always minimized the nature and scope of the problem, stated that the problems were being addressed, and even indicated that it took greater than necessary corrective measures to protect the public.

9. After the Company's problems escalated in late 2008, the FDA issued a Warning Letter to Caraco. Caraco's November 3, 2008, announcement that it had received the Warning Letter was a partial materialization of the undisclosed risks inherent in pushing rapid drug production at the expense of quality and regulatory compliance and revealed: that at the time its prior statements were made, Caraco had not been substantially cGMP compliant; that the Company had not responded to the FDA's observations in the June 2008 Form 483 accordingly;

that the Company had not remedied previous observations from the FDA; and that as a result, the Company could face regulatory sanctions.

10. On this news over the Warning Letter, over the next three days, shares of Caraco declined by $2.26 per share, or 22.22%, to close on November 5, 2008, at $7.91 per share, on unusually heavy volume.

11. Caraco, however, continued to represent to investors that the Company had responded to all the observations made in the Form 483 and that Caraco had taken "corrective actions," which were "substantially completed." The full truth regarding the actual condition of the Company's operations was not revealed. As stated by the confidential witnesses, and as confirmed by the subsequent seizure of ***all*** of the Company's manufactured drugs, the Company was plagued by rampant, systemic manufacturing, QA and QC failures that were not being addressed properly. The Warning Letter did not fully apprise the public of the full extent to which Caraco was egregiously noncompliant with cGMP, as confirmed by the confidential witnesses.

12. After the issuance of a Warning Letter by the FDA on October 31, 2008, Caraco also publicly announced that it had brought in new management to address the problems. Without correction of the noted deficiencies, Caraco could not obtain ANDA approvals. Unfortunately, as several witnesses confirmed, the new managers were from Sun Pharma and entirely focused upon increased production – and not upon doing what it took to rectify the serious and persistent deficient conditions noticed by the FDA. When one confidential witness complained that improved Standard Operating Procedures could not be designed and implemented in light of the production "over anything else" attitude of the two new Sun Pharma-

installed managers (Sandeep Mehta and Sunil Ajmera), the confidential witness was told by Defendant Movens that Movens's "hands were tied" because he reported to Sun Pharma.

13. Caraco responded to the FDA's Warning Letter in late November 2008. Upon acknowledging receipt of the response, in late December the FDA noted: "I would like to reiterate a concern that we discussed during our phone call [on December 4, 2008]. There is a real problem regarding your processes that are yielding tablets of varying sizes. The fact that...there are a number of customer complaints regarding tablet size for a variety of products is disconcerting. Validated processes should yield product of consistent quality. ***This issue needs to be resolved as it has been going on quite some time***." (Emphasis added).

14. On March 31, 2009, the truth was further partially revealed as Caraco further disclosed that it had commenced a voluntary recall, with the knowledge of the FDA, of certain tablets manufactured by the Company because the tablets might have differed in size and therefore could have more or less of the active ingredient.

15. This news sent Caraco's shares down $1.03 per share, more than 22%, to close on March 31, 2009, at $3.52 per share, on unusually heavy volume. While the drug recall revealed some manufacturing problems at the Company, the full extent to which Caraco was plagued by manufacturing and compliance failures was not revealed to the public.

16. On June 24, 2009, the FDA could no longer give Caraco time to cure the serious and potentially life-threatening problems which had been ongoing for "quite some time." On that day, the United States Attorney for the Eastern District of Michigan filed a complaint for forfeiture of adulterated articles of drug on behalf of the United States directed at all articles of drug located at Caraco's Elijah McCoy, Farmington Hills or Wixom, Michigan facilities.

17. Finally, on June 25, 2009, investors learned the true extent of Caraco's severe and systemic manufacturing problems. That day, the FDA announced that U.S. Marshals had seized drug products manufactured by Caraco from the Company's facilities. According to the FDA, this action followed Caraco's continued failure to meet the FDA's cGMP requirements, which assure the quality of manufactured drugs. The FDA stated that through the seizure, it sought to immediately stop the company from further distributing drugs until there is assurance that the firm complies with good manufacturing requirements.

18. On this news, shares of Caraco declined $1.79 per share, approximately 43%, to close on June 25, 2009, at $2.39 per share, on unusually heavy volume.

II. JURISDICTION AND VENUE

19. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act (15 U.S.C. §78aa).

21. Venue is proper in this Judicial District pursuant to 28 U.S.C. §1391(b) and Section 27 of the Exchange Act (15 U.S.C. §78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the preparation and dissemination of materially false and/or misleading information, occurred in substantial part in this District. Additionally, Caraco is a Michigan corporation and maintains its principal executive offices within this Judicial District.

22. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

23. Lead Plaintiff Tushar Amin, as set forth in the certification filed with the Court in connection with his motion to be appointed lead plaintiff, see Docket Item #8 at Exhibit B, incorporated by reference herein, purchased Caraco common stock during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

24. Plaintiff Kevin Koziatek, as set forth in the certification filed with the Court in connection with his motion to be appointed lead plaintiff, see Docket Item #7 at Exhibit A, incorporated by reference herein, purchased Caraco common stock during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

25. Plaintiff Jonathan Wilkof, as set forth in the certification previously filed in his initial complaint, see Docket Item #1, incorporated by reference herein, purchased Caraco common stock during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

26. Defendant Caraco is a Michigan corporation and maintains its principal executive offices at 1150 Elijah McCoy Drive, Detroit, Michigan 48202. Caraco was incorporated in the State of Michigan in 1984 and became a public company in 1997. The Company's executive

offices and manufacturing facilities during the Class Period were at all times located at 1150 Elijah McCoy Drive, Detroit, Michigan. During the Class Period, Caraco had in excess of 660 full time equivalent and contract employees engaged in research and development, manufacturing, quality assurance, quality control, administration, sales and marketing, materials management, facility management and packaging. According to Caraco's FY 2008 Form 10-K, most of its scientific and engineering employees had prior experience with pharmaceutical or medical products companies, including Sun Pharma.

27. Defendant Daniel H. Movens ("Movens") was, at all relevant times, Chief Executive Officer ("CEO") and a director of Caraco. Movens became CEO of Caraco in or around May 2005. Movens was, during the Class Period, a member of Caraco's Quality Review Board which exercised oversight over the unit monitoring manufacturing quality at Caraco. Movens became CEO of Caraco in or around May 2005. Movens was, during the Class Period, a member of Caraco's Quality Review Board which exercised oversight over the unit monitoring manufacturing quality at Caraco. Defendant Movens signed Caraco's FY 2008 Form 10-K, filed with the SEC on June 10, 2008, Caraco's Form 10-Q for the first quarter of FY 2009, filed with the SEC on July 25, 2008, Caraco's Form 10-Q for the second quarter of FY 2009, filed with the SEC on October 24, 2008, Caraco's Form 10-Q for the third quarter of FY 2009, filed with the SEC on February 3, 2009 and Caraco's FY 2009 Form 10-K, filed with the SEC on June 15, 2009. Defendant Movens also directly received all Form FDA 483s sent by the FDA to Caraco as a result of its inspections of Caraco's facilities before and during the Class Period and prepared and sent a detailed response in writing to each observation contained with those Form FDA 483s. Movens also directly received the October 31, 2008 Warning Letter from the FDA

and prepared and sent a detailed response in writing to the Warning Letter. Movens also corresponded and meet directly with FDA officials regarding Caraco's compliance with cGMP on numerous other occasions. Movens was also personally involved in multiple internal company meetings addressing the Caraco's failure to meet the FDA's cGMP and spoke on numerous occasions with senior managers involved in the manufacturing and packaging of Caraco products regarding Caraco's massive and ongoing manufacturing deficiencies as set forth below.

28. Defendant Dilip Shanghvi was, at all relevant times, Chairman of Caraco's Board of Directors. Defendant Shanghvi is also the founder of Sun Pharma and has been Sun Pharma's Chairman and Managing Director since Sun Pharma's inception in 1993. Defendant Shanghvi signed Caraco's FY 2008 Form 10-K, filed with the SEC on June 10, 2008 and Caraco's FY 2009 Form 10-K, filed with the SEC on June 15, 2009.

29. Defendants Movens and Shanghvi are collectively referred to hereinafter as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Caraco's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations

which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

30. Defendant Sun Pharma was, at all relevant times, the majority and controlling shareholder of Caraco. Sun Pharma is one of India's leading pharmaceutical companies, manufacturing and supplying formulation and bulk drugs in both the Indian and international markets, including the United States, and is publicly traded on Indian stock exchanges. During the Class Period, Sun Pharma beneficially owned approximately 70% of the outstanding shares of Caraco.

IV. OVERVIEW OF FDA REGULATIONS AND THE MARKET FOR GENERIC DRUGS

A. The FDA Approval Process

31. Caraco is engaged primarily in the business of developing, manufacturing, marketing and distributing generic and private-label pharmaceuticals to the nation's largest wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers, throughout the U.S. These products are intended to treat a variety of disorders including but not limited to the following: hypertension, arthritis, epilepsy, diabetes, psychosis, depression and chronic pain.

32. In the United States, the FDA requires a generic drug to be identical – or bioequivalent – to its referenced brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are required to be chemically identical to their branded counterparts, they are typically sold at substantial discounts from the price of the referenced brand name product.

33. A pharmaceutical company may apply to manufacture and sell a generic version of a branded drug previously approved by the FDA by submitting an ANDA. 21 CFR 314.94. Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must state that the route of administration, dosage form, and strength of the proposed drug product are the same as those of the reference listed drug. 21 CFR 314.94. All generic drugs approved by FDA must also have the same quality, strength, purity and stability as brand-name drugs. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs.

34. When a pharmaceutical company submits an ANDA to the FDA, it must include information about all manufacturing, packaging and control sites associated, or that will be associated, with the manufacture and sale of the generic drug identified in the application. The applicant must also indicate whether these facilities are ready for inspection and, if not, when they will be ready. The applicant must also certify, through a responsible official or agent, that it will comply with all applicable laws and regulations that apply to approved applications, including, but not limited to, current good manufacturing practice regulations as set forth in 21 CFR Parts 210 and 211 or applicable regulations, Parts 606, and/or 820. The applicant also certifies it will comply, once it receives approval from the FDA, with all regulations, as set forth in 21 CFR 314.80 and 314.81 regarding the reporting of adverse drug experience, including an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event

occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

B. FDA Inspections of Generic Drug Manufacturers

35. Prior to approving a pharmaceutical company's application to sell and manufacture a generic drug under an ANDA, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether the company's systems, processes and procedures comply with cGMP and other FDA regulations. During these reviews and inspections, the company must demonstrate compliance with cGMP as well as provide substantial evidence of the safety and efficacy of the generic drug submitted for approval. The cGMPs mandate, among other things, proper design, monitoring, and control of manufacturing processes and facilities. The systems that FDA investigators focus on correspond with the general scheme of pharmaceutical manufacturing operations: (l) Quality; (2) Facilities and Equipment; (3) Materials; (4) Production; (5) Packaging and Labeling; and (6) Laboratory Controls. Adherence to the cGMP requirements is intended to assure the identity, strength, quality, and purity, of drug products by requiring that pharmaceutical manufacturers adequately control manufacturing operations. This includes, among others, establishing strong quality managements systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. If adequately implemented, these systems of control aid in preventing instances of contamination, deviations, failures, and errors, and/or assure that drug products meet quality standards before drug products are sold to consumers who would otherwise be

unknowingly placed at risk and subjected to potentially serious health hazards if non-conforming products were distributed and consumed.

36. Continuing compliance with the FDA's cGMPs is expected and required of all companies selling generic drugs in the United States, whatever their place of manufacture. The FDA regularly inspects pharmaceutical manufacturing facilities worldwide to evaluate whether a manufacturer is adhering to these requirements. Notwithstanding these regular inspection, the responsibility to comply with cGMP remains with the management of the company selling drugs for human consumption in the United States. In addition to periodic inspections, and inspections related to ANDAs, the FDA relies upon reports of potentially defective drug products from the public and the industry, often using such reports to identify sites for which an inspecting or investigation is needed. As indicated above, a manufacturer submitting an ANDA must certify it will report adverse drug experiences regarding its products to the FDA so that the FDA can consider whether further action on its part, including follow-up inspection, is warranted.

37. When an FDA inspection demonstrates that a company is not following cGMP, the FDA issues a FDA Form 483 Inspectional Observations to the company ("Form 483"), which memorializes the observations of non-compliance with cGMP regulations observed during the inspection and is "intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts." See Investigations Operations Manual 2009, Reports of Observations, 5.2.3. Form 483s are issued in the course of pre-approval inspections, post-approval inspections and follow-up inspections based on previous inspections or adverse drug experiences reported to the FDA. In the context of a post-approval inspection, a failure to

correct conditions observed in a Form 483 may result in an FDA Warning Letter or other action. In the context of a pre-approval inspection, a failure to correct conditions in a Form 483 will result in the rejection of the ANDA. Inspections that document serious and pervasive cGMP deficiencies are classified as Official Action Indicated ("OAI") by the District Office. Before concluding the inspection and issuing the Form 483, the FDA inspectors meet with top ranking members of management to discuss their observations, and to explain the serious nature of the cGMP violations and of possible sanctions that it faces. Investigations Operations Manual 2009, Discussions with Management 5.2.7.

38. The Form 483 is issued to the highest ranking member of management who attended the meeting with the FDA inspectors. A copy of the Form 483 should also be forwarded to the top official of the firm if that official did not previously receive the Form 483. Investigations Operations Manual 2009, Responsible Individuals 5.7.4. Usually a company responds to a Form 483 by submitting a corrective action plan to the FDA that outlines what the company will do to correct the observed problems. Frequently, follow-up compliance inspections by the FDA are conducted to determine if the firm's corrective action plan has been implemented.

39. The consequences of severe and/or continued violations of cGMPs can be devastating to a drug manufactures business and its reputation. As set forth above, the failure to comply with cGMP with regard to drugs manufactured for human consumption poses a severe risk to public health. As described herein, in extreme situations, the FDA can seek injunctive relief or seizure of adulterated and defective drugs to address and stop cGMP violations. Both seizure and injunction cases often lead to and result in the issuance of court orders specifically

requiring the manufacturers to refrain from the continued manufacture of drug products in violation of cGMP requirements and to take immediate steps to correct cGMP violations, such as hiring outside experts, writing and/or implementing new procedures, and/or conducting extensive training of employees. In addition to the obvious stigma of such FDA action and the grave negative consequences for the commercial perception that customers and consumers will have of the quality of a manufacturer's products, the FDA may withhold approval of pending new drug applications or export certificates until such time as the manufacturer corrects the violations. Moreover, other federal agencies may even take the FDA's action into account when considering whether to award contracts.

C. The Market for Generic Drugs

40. The sales of generic pharmaceuticals have increased in recent years due to a number of factors, including the increased number of formerly patented drugs which have become available to generic competition, changes in governmental and third-party payer healthcare reimbursement policies designed to encourage cost containment through the purchase of cheaper generic versions of branded drugs, increased acceptance of generic drugs by health care professionals and consumers, laws which permit or require substitution of generic drugs by pharmacists, and the enactment of the ANDA procedures for obtaining FDA approval to manufacture generic prescription drugs.

41. The market for generic drugs is large and competitive. According to IMS Health, one of the world's leading providers of market intelligence to the pharmaceutical and healthcare industries, global generic products generated $78 billion in audited sales in the 12 months ending with September 2008. During that period, the United States was the world's largest generic drug

market with 42% of global sales and generic products accounted for 71.5 % of the total US pharmaceutical market. The generic market is expected to grow as products that currently generate $137 billion in sales, including Lipitor®, Plavix®, and Seretide®, are expected to face generic competition over the next five years.

42. A pharmaceutical company that receives FDA approval for the manufacture and sale of a generic version of a branded drug in advance of other competitors may benefit from a 180 day period of exclusivity in the sale of the product pursuant to the Hatch-Waxman Amendments to the Food, Drug and Cosmetics Act. In order to benefit from such exclusivity, a manufacture must include in its ANDA a patent certification described in section 505(j)(2)(A)(vii) of the Act. The certification must make one of the following statements: (I) no patent information on the drug product that is the subject of the ANDA has been submitted to FDA; (II) that such patent has expired; (III) the date on which such patent expires; or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved New Drug Application ("NDA") to which the ANDA refers. The submission of an ANDA for a drug product that is claimed in a patent is an infringing act if the drug product that is the subject of the ANDA is intended to be marketed before the expiration of the patent and, therefore, may be the basis for patent infringement litigation. As a result, in certain circumstances, an ANDA applicant whose ANDA contains a paragraph IV certification is protected from competition from subsequent generic versions of the same drug product for 180 days after either the first marketing

of the first applicant's drug or a decision of a court holding the patent that is the subject of the paragraph IV certification to be invalid or not infringed. This marketing protection is commonly known as "180-day exclusivity."

43. A manufacturer who obtains "180-day exclusivity" on a generic drug can enjoy significant financial rewards during this period as well as build its market share before competitors can enter the market. Subsequent entrants generally do not earn such significant rewards. According to the FDA, drawing on IMS retail sales data, the first generic competitor prices its products only slightly lower than the brand-name manufacturer. The appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price. As additional generic manufacturers market the product, the prices continue to fall, but more slowly. For products that attract a large number of generic manufacturers, the average generic prices can fall to 20% or lower of the price of the branded drug. Investors, accordingly, look particularly for pharmaceutical companies that have received, or anticipate receiving, 180 day exclusivity on a generic drug.

44. Due to the inevitable expiration of the exclusivity period on a given generic drug, investors carefully consider, in addition to existing sales on already approved drugs, the "pipeline" of new product launches anticipated by a pharmaceutical company and the potential for exclusivity on such products when approved by the FDA. An important factor in evaluating the "pipeline" is the number of ANDAs submitted to the FDA by a particular pharmaceutical company.

45. Even if 180 day exclusivity is not available on a given generic drug, the number of ANDAs submitted by a given manufacturer is material to investors because it represents an

important factor in evaluating both present sales and the potential for additional sales on generic drugs that the FDA may subsequently approve for sale. Generally, the more robust the pipeline of generic drugs the manufacturer has applied to manufacture and sell, the greater its present sales and potential for future growth. This is particularly true for pharmaceutical companies that, like Caraco, focus on the manufacture and sale of generic drugs that, even where 180-day exclusivity is not available, generally have less competition because of barriers to entry, such as difficult-to-formulate drugs or drugs made from difficult-to-source materials.

V. CARACO IMPLEMENTS A STRATEGY TO RAPIDLY EXPAND THE COMPANY'S BUSINESS IN THE COMPETITIVE GENERIC DRUGS MARKET

A. Sun Pharma Asserts Dominance over Caraco's Operations

46. Beginning in 1997, through a series of stock purchase, product agreement, marketing, and distribution and sales agreements and transactions, Sun Pharma became a large, majority shareholder of Caraco – claiming a 70% beneficial ownership of Caraco as of March 31, 2008 and a 74% beneficial ownership of Caraco as of March 31, 2009:

a. In 1997, Sun Pharma, pursuant to a stock purchase agreement, made an initial investment of $7.5 million in Caraco in exchange for the purchase of 5.3 million common shares of Caraco. According to its Form 10QSB, filed shortly before completion of the stock purchase agreement, Caraco expected to immediately commence bankruptcy proceedings if it did not obtain the additional equity capital from Sun Pharma.

b. In August of 1997, Caraco entered into an agreement that obligated Sun Pharma to transfer to Caraco the technology formula for up to 25 mutually agreed generic pharmaceutical products over a period of five years though

August 2003. Caraco exchanged 544,000 shares of its common stock for each such technology transfer when bio-equivalency studies for each ANDA was successfully completed and 181,333 shares for each technology transfer of a Drug Efficacy Study Implementation Program (DESI). Sun Pharma delivered to Caraco 13 of the possible 25 products under this agreement.

c. In November 2002, Caraco entered into a new product agreement with Sun Pharma, Inc., a wholly owned subsidiary of Sun Pharma ("Sun Global"). Under this agreement, Sun Global agreed to provide Caraco with 25 new mutually agreed upon generic drugs over a five year period for sale within the United States and its territories and possessions, including Puerto Rico. For each generic drug transferred, Caraco agreed to provide 544,000 shares of Series B Preferred Stock to Sun Global. While non-voting shares, these preferred shared were convertible into common shares after three years on a one to one basis. This products agreement provided that the products were to be selected from time to time by the mutual agreement of Sun Global's and Caraco's management, with the concurrence of Caraco's Independent Committee of the Board of Directors. In 2004, the products agreement with Sun Global was amended by the Independent Committee to eliminate the requirement for approval by the independent committee. In its place, the amended products agreement provided that each product selected satisfy certain criteria developed by management and approved by the Independent

Committee. Pursuant to the products agreement, as amended, Caraco selected a total of 25 out of a possible 25 products.

d. During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,679,066 stock options from two former directors and a significant shareholder. Sun exercised the options in the fourth quarter of 2004.

e. On March 31, 2007 Sun Global converted 1,632,000 shares of Series B Preferred stock into 1,632,000 shares of common stock.

f. In Fiscal 2007, Caraco entered into a three-year marketing agreement with Sun Pharma. Under this marketing agreement, Caraco can purchase, at Sun Pharma's option, selected product formulations from Sun Pharma and market and distribute those products as part of its product offerings in the U.S., its territories and possession, including Puerto Rico.

g. During the fiscal year ended March 31, 2008, Sun Global converted 4,352,000 shares of Series B Preferred stock into 4,352,000 shares of common stock. As of March 31, 2008, Sun Pharma's beneficial ownership of Caraco was 70%.

h. During the fiscal year ended March 31, 2009, Sun Global converted 4,896,000 shares of Series B Preferred stock into 4,896,000 shares of common stock. As of March 31, 2009, Sun Pharma's beneficial ownership of Caraco was 74%.

i. In Fiscal 2008, Caraco entered into a three-year distribution and sale agreement with Sun Pharma. Under this distribution and sale agreement, Caraco can purchase, at Sun Pharma's option, selected product formulations

which have been filed under Paragraph IV certification process with the FDA by Sun Pharma. Pursuant to its terms, Sun Pharma agrees to indemnify Caraco for any risk, including litigation challenges with respect to claims of patent infringement, beyond Caraco's profit percentage as set forth in the agreement. The license granted with respect to any product included within this distribution and sale agreement ends upon the end of the 180 day exclusivity period, or a non-appealable court decision, or until a third generic manufacturer launched the product, whichever is later, or until a settlement is reached, at which time the product will become part of the 2007 marketing agreement set forth above.

47. Sun Pharma also asserted control over Caraco by installing its own directors/officers on to Caraco's Board of Directors. During the Class Period, the following ***five out of nine*** Caraco directors were affiliated with Sun Pharma:

a. Defendant Dilip Shanghvi, Chairman of Caraco's Board of Directors, is the founder of Sun Pharma and was Sun Pharma's Chairman and Managing Director since Sun Pharma's inception in 1993.

b. Gurpartap Singh Sachdeva, Senior Vice President – Business Strategies and a Caraco director, was the Manager of Bulk Drugs for Sun Pharma from May 1998 to September 2000.

c. Jitendra N. Doshi, a Caraco director who at times assumed various leadership positions at Caraco, also served during the Class Period as the Executive

Director of Sun Pharmaceutical Industries, Inc. ("Sun Global"), a wholly-owned subsidiary of Sun Pharma.

d. Sailesh T. Desai, a Caraco director, was also a "Wholetime Director" or "Executive Director" of Sun Pharma since 1999.

e. Sudhir V. Valia, a Caraco director, was also a "Wholetime Director" or "Executive Director" of Sun Pharma since 1994. Mr. Valia was also the brother-in-law of Dilip Shanghvi.

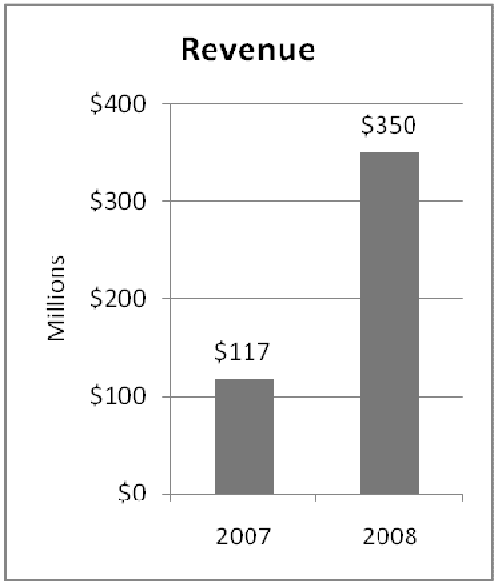
48. By the beginning of the Class Period, it was clear that Sun Pharma was exercising significant control over Caraco's operations. As set forth below and corroborated by confidential witness testimony, Sun Pharma's control over Caraco's operations was evidenced by, *inter alia*, Sun Pharma installing two senior employees at Caraco in or around December 2008 who exercised broad control over Caraco's manufacturing operations.

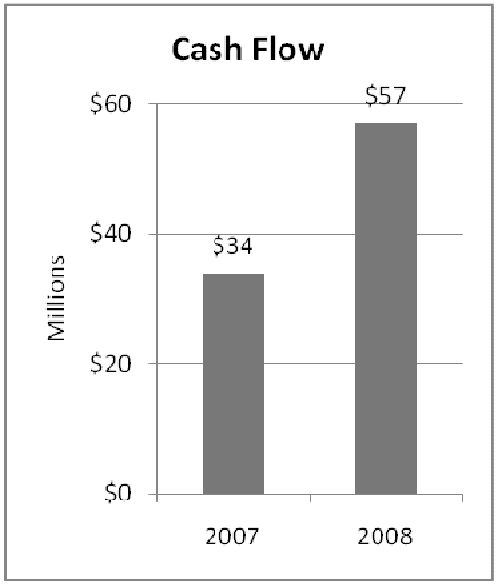
B. At Movens's Direction and Propelled by Sun Pharma, Caraco Experiences Unprecedented Growth from 2005 to 2008

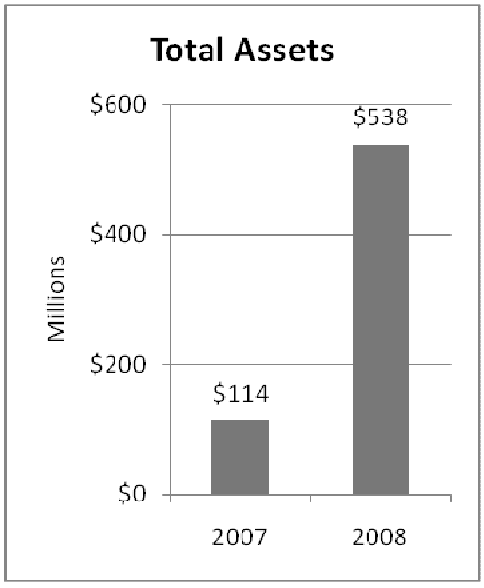
49. Sun Pharma was instrumental in the growth of Caraco leading up to the Class Period mostly through the provision of equity capital, generic drug formulations, and research and development. Pursuant to various oral agreements between Caraco and Sun Pharma, Sun Pharma supplied Caraco with a substantial portion of its raw materials and assisted Caraco in acquiring machinery and equipment to enhance its production capacities.

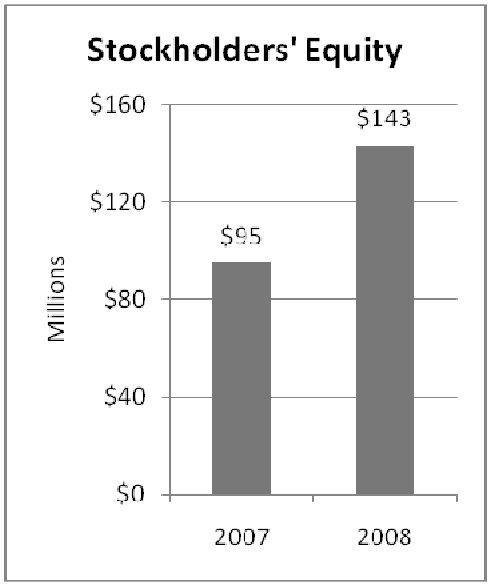
50. Ostensibly, the relationship paid off handsomely for both companies. Both Caraco and Sun Pharma reported monumental growth by the start of and during the Class Period. For example, Caraco's FY 2008 ending March 31, 2008, marked Caraco's ***sixth consecutive year of exponential sales growth***. Indeed, sales increased ***199% to a record $350 million*** from

$117 million in FY 2007. The Company saw its gross profit for FY 2008 ***increase nearly $27 million*** to $84.7 million. Net sales growth and continued decrease in operating expense as a percentage of sales drove net income gains over FY 2007 and the Company ***earned net income of $35.4 million in FY 2008 compared to $26.9 million in FY 2007***. Caraco's remarkable growth is charted in the below graphical depictions:

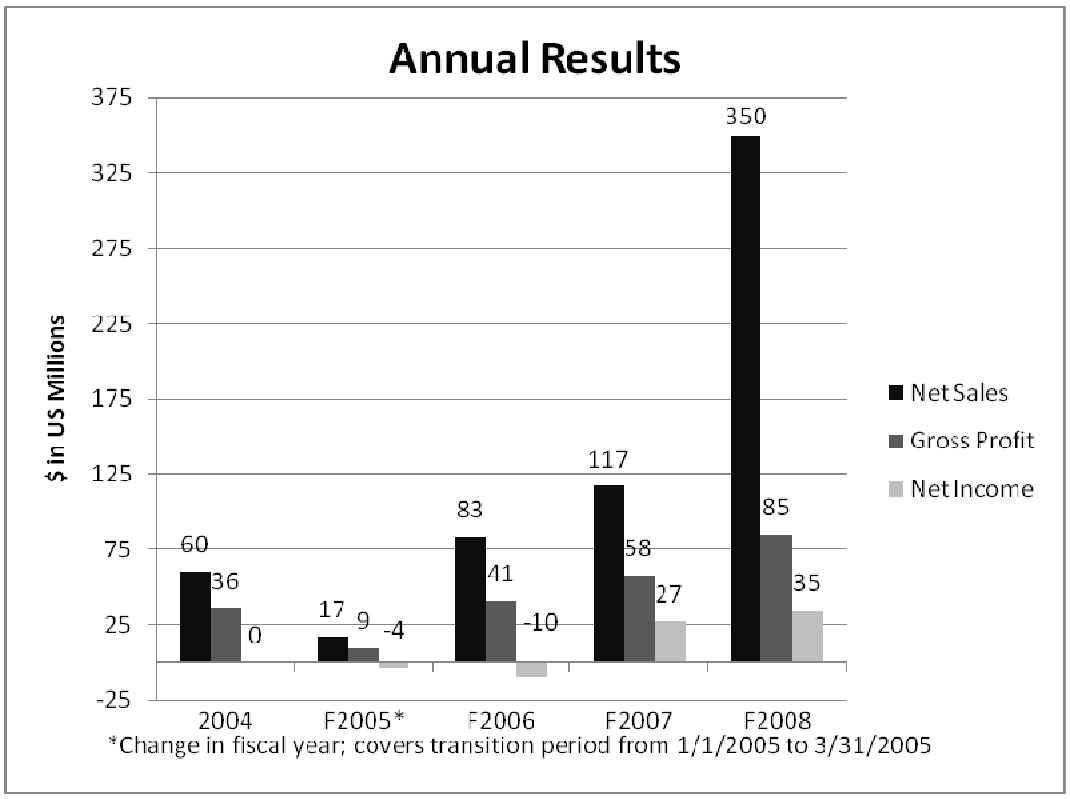


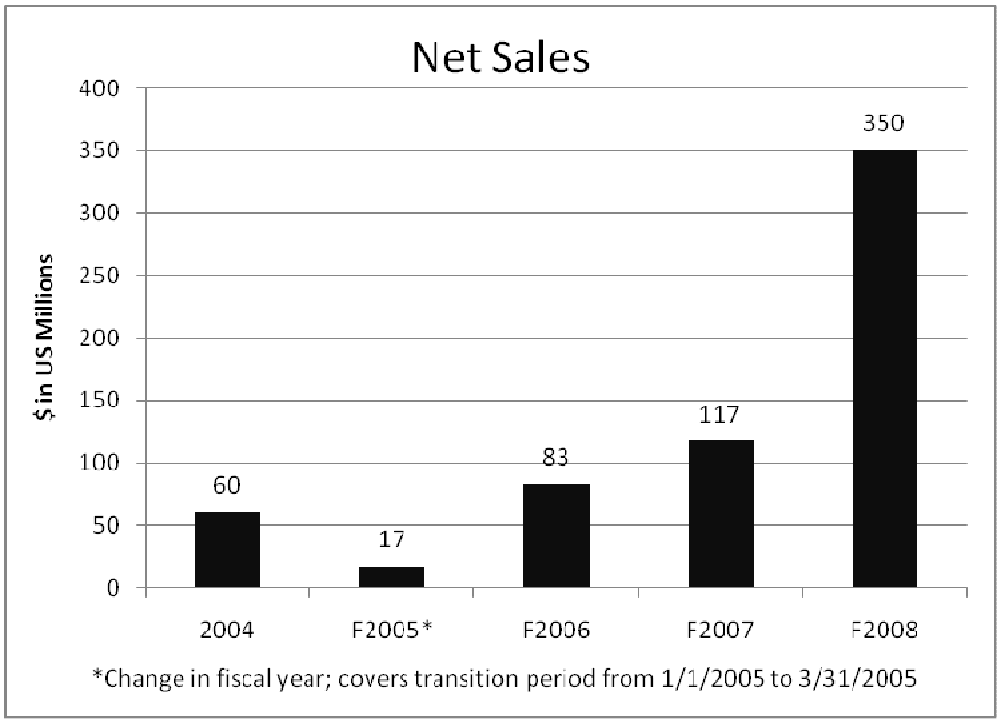


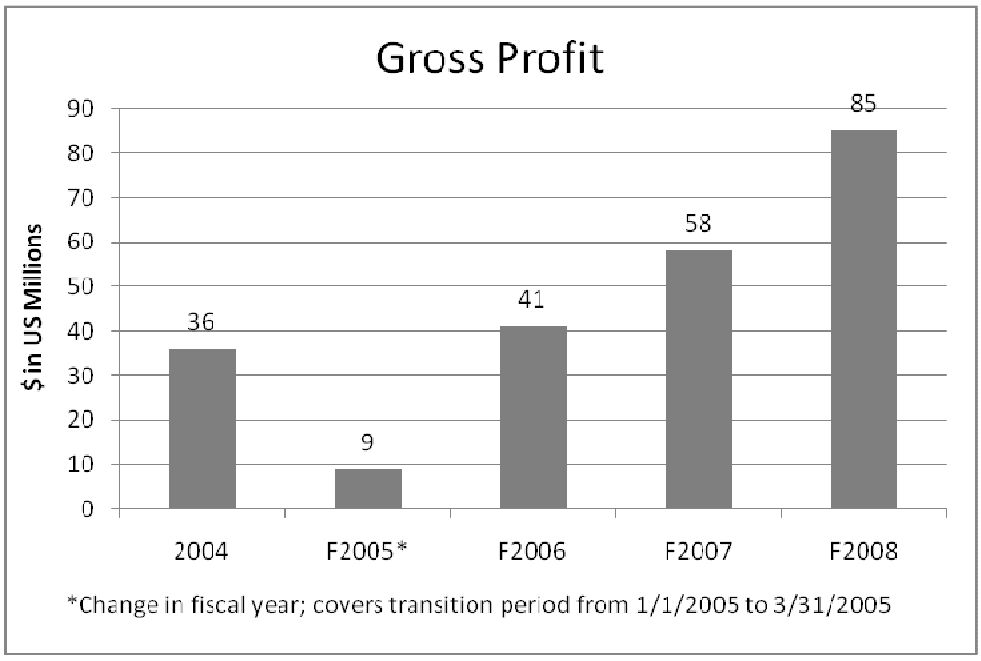




51. Caraco's growth in FY 2008 was even more substantial when compared to its performance since FY 2006. The $350 million in FY 2008 net sales, $84.7 million in gross profit, and $35.4 million in net income, represented a staggering increase over its FY 2006 results of $82.8 million in net sales, $40.9 million in gross profit, and $10.4 million net loss. The following charts, derived from information published in Caraco's October 2008 Investor Presentation entitled "Driving Value," depict Caraco's rapid growth in recent years:







52. Defendant Movens was at the center of Caraco's remarkable and rapid growth. Throughout the Class Period, Movens publicly trumpeted the phenomenal growth in Caraco's

operations. For example, in a letter to Caraco shareholders included in the Company's FY 2008 Annual Report, Defendant Movens touted:

> ***It has been a very positive and eventful year for Caraco, as Fiscal 2008 was one of the most dynamic years we have experienced to date. Our portfolio of products continued to grow, both from products we manufacture and products that we market and distribute for Sun Pharmaceutical Industries Ltd. ("Sun Pharma") and Sun Pharma Global Inc. ("Sun Global")***. In addition to significantly increasing our revenues and income, we also focused on managing change, effecting change and streamlining our processes. This culture of continuous improvement will position us to sustain our growth in the competitive pharmaceutical market place. I firmly believe that we are prepared to sustain the growth we have experienced and will further fulfill the promise we have made to our shareholders.
>
> During the year, we delivered a solid performance in what is now a diversified portfolio of products, ***resulting in our sixth consecutive year of exponential sales growth***. Our overall profitability increased for the year as we invested in the infrastructure required to carry us into the future. In the generic pharmaceutical sector, new products are the cornerstone of future growth. As such, we continue to invest in research and development projects in order to expand our portfolio of products. Our continuing efforts in development will only strengthen our prospects for both the near and long term. ***Our relationship with Sun Pharma for distributed products contributed significantly to our top-line growth. We continue to believe that Sun Pharma is a partner with a proven track record which has provided us with a strong portfolio of valuable products.*** During the year, the technology for all twenty-five products under the technology transfer agreement with Sun Global has been consummated and the agreement fulfilled.
>
> * * *
>
> Our success in Fiscal 2008 was built on the foundation of our past years' hard work, focus on our core business, and dedication to and execution of our strategic initiatives. We believe we have strengthened our culture and laid the foundation for future growth in Fiscal 2009 and thereafter.
>
> Best Regards,
>
> s/ Daniel Movens
> Chief Executive Officer

(Emphasis added).

53. Of course, Caraco was not the sole beneficiary of the relationship. Caraco's substantial growth drove Sun Pharma's financial results for FY 2008 ending March 31, 2008. The benefit conferred on Sun Pharma was illustrated in a June 2, 2008, article from the *World Markets Research Centre*, authored by Anupama Bharath, entitled, "Sun Pharma's U.S. Presence Boosts Profits by 90% in FY 2007/08." Therein, the article stated:

> Backed by the performance of its U.S. subsidiary's record sales and its strong foothold in the domestic market, Sun Pharmaceuticals has posted a 57% increase in sales for FY 2007/08.
>
> Indian drug firm Sun Pharma has posted sales growth of 57% year-on-year (y/y) to 33.56 billion rupees ($793US million) for FY 2007/08, bolstered by its U.S. generic business. Net profit and profit before tax (PBT) posted increases of 90% and 92% to 14.87 billion rupees and 15.99 billion rupees, respectively, while R&D for the year also increased by 16% to 2.99 billion rupees. Although the company's strong performance in the United States boosted its performance, the domestic market has always been a revenue generator for the company. FY 2007/08 was no different, with domestic formulation sales at 14.76 billion rupees, contributing to 43% of Sun Pharma's overall sales for the year.
>
> **Global Insight Perspective**
>
> **Significance** Sun Pharma's net profit for the fiscal year increased by 92%, achieving a 57% increase in sales.
>
> **Implications** FY 2007/08 has been a significant year for Sun Pharma's U.S. presence, with product exclusivities and U.S. subsidiary Caraco's record performance boosting sales and profit, especially in the fourth quarter of the fiscal year. The company's traditionally strong domestic formulations business has also performed well, achieving a 43% contribution towards overall sales.
>
> **Outlook** Sun Pharma has set a guidance of 25% growth in sales for FY 2008/09. It is expecting to file for 30 Abbreviated New Drug Applications (ANDAs) over the next fiscal year, while 48 pre-existing ones are expected to drive the guidance for the coming year, despite some ANDA's failing to gain approval . . . .

> Results for the fourth quarter of FY 2007/08 have driven the company's fiscal year performance. Sales increased by 129% to 12.57 billion rupees, while net profit and PBT for the quarter rose by incredible rates of 225% and 222% to 7.23 billion rupees and 7.67 billion rupees, respectively.
>
> * * *
>
> **Caraco Boosts Sun Pharma's U.S. Generics Sales**
>
> The Indian firm's U.S. subsidiary, Caraco Pharmaceuticals, has posted record sales for FY 2007/08, surging by 99% to $350US million, while net income rose by 31% to [$35.4US] million for the year. Like Sun Pharma, Caraco's fourth-quarter results led its performance over the fiscal year. Fourth-quarter sales were at $192US million, up a massive 481%, while profits for the quarter reached [$11.5US] million, up 21%. The launch of pantoprazole and oxcarbazepine through Caraco led sales for the latter in the fourth quarter of FY 2007/08.
>
> Sun Pharma and Caraco's strong performances for the year have been boosted by product exclusivities and at-risk launches. Shared exclusivity for Novartis's (Switzerland) epilepsy drug Trileptal (oxcarbazepine) and Eli Lilly's (U.S.) cancer drug Gemzar (gemcitabine) are reflective of Sun Pharma's Para IV filing successes. It also launched generic versions of Wyeth's (U.S.) Protonix (pantoparzole) and MedImmune's (U.S.) Ethyol (amifostine injection) even though patents on both products are yet to expire. Other generic launches that have strengthened Sun Pharma's U.S. product pipeline over the year include Demadex (torsemide) and delayed-release tablets of generic Depakote (divalproex sodium).
>
> **Outlook and Implications**
>
> Sun Pharma has set a guidance of 25% growth in sales for FY 2008/09, and hopes to file 30 ANDAs in addition to the 48 already filed. Caraco's guidance is in line with Sun Pharma's upon completion of the expansion of its facilities by the end of the year . . .

C. Despite Reports of FDA Inspection Observations Coinciding with Caraco's Rapid Expansion from 2005 to 2008, Caraco Allays Public Concerns by Downplaying the Significance of the FDA's Observations

54. While the FDA conducted at least three inspections of Caraco's facilities between March 2005 and August 2007, in its filings with the SEC the Company briefly noted receipt of FDA Form 483s while simultaneously minimizing the significance of any FDA observations. In

2005 to 2006, the Company casually shrugged off the FDA Form 483s as "not material," and later in 2006 to 2007 Caraco touted that the Company had "responded accordingly" to the Form 483s and "remain[s] substantially cGMP compliant." Caraco's assurances allayed investor fears and preempted public suspicion.

55. For example, the Company's Transition Report on Form 10-K/T filed with the SEC on June 13, 2005, and its Quarterly Report on Form 10-Q filed with the SEC on August 9, 2005, acknowledged that the Company was issued a Form 483 following a May 2005 inspection but downplayed the significance, stating "we believe that the observations are not material." In regards to the Form 483 that Caraco stated was "not material":

a. On June 10, 2005, Caraco provided a 23-page response that concluded "most of the observations presented in the FDA 483 were isolated events and not reflective of overall systemic failures." Caraco further assured the FDA and the public that the Company had "taken corrective action where necessary" regarding other observations and had "reviewed and investigated the systems and procedures affected" and "immediately corrected or addressed" the issues when identified.

b. In a letter from Movens to Ms. Putz at the Detroit District Office of the FDA on August 5, 2005, he confidently stated, "[c]onsidering the actions outlined in this response in conjunction with our previous response, we believe that we are in substantial compliance with cGMPs."

56. Additionally, the Company's Quarterly Reports on Form 10-Q filed with the SEC on July 27, 2006 and October 25, 2006, both noted that following a June 2006 inspection the

Company was provided observations on a Form 483. However, the Company simultaneously assured the public that "[t]he Company has responded appropriately" and "believes that the observations are not material and we remain substantially cGMP compliant."

57. Furthermore, the Company's Quarterly Report filed with the SEC on October 25, 2007, noted that the FDA completed an inspection in August 2007 and provided the Company with "***an*** observation on FDA Form 483." (Emphasis added.) However, Caraco noted that "[t]he Company has responded accordingly, and we believe that we remain substantially cGMP compliant." In regards to that Form 483, in a September 26, 2007 letter Defendant Movens represented that Caraco had previously identified the "gap" in its standard operating procedures identified in the Form FDA 483 and had revised its procedures to address them, effective September 26, 2007.

58. Caraco's statements minimizing the FDA's observations led the public to believe that any FDA observation was "not material," limited in scope, that any such minimal concern was easily addressed by the Company, and that, overall, Caraco was "substantially cGMP compliant."

VI. DURING THE CLASS PERIOD, DESPITE INTENSIFYING FDA SCRUTINY OVER MANUFACTURING OPERATIONS, CARACO CONTINUES TO ALLAY PUBLIC CONCERNS BY DOWNPLAYING THE FDA'S OBSERVATIONS AND BY TOUTING ITS ONGOING EFFORTS TO COMPLY WITH cGMP

59. Just prior to the Class Period, between February 14, 2008 and March 6, 2008, the FDA conducted a limited inspection in response to the Company's Field Alert and notification of intent to recall seven lots of Mertformin HCL Tablets, USP, 1000mg, and complaints regarding Metformin HCL tablets. According to the FDA, the reason for the recall was that "some tablets

are undersized and some are oversized, which will result in the patient not receiving the expected dose."

a. On March 6, 2008, the FDA issued a Form FDA 483 containing four observations. Not only did the FDA observations note the presence of defective tablets, including over and under sized tablets, the FDA noted that Caraco's records lacked complete information relating the production and control of each batch – making it difficult to determine the cause of the tablet defects, the magnitude of the weight variations in the tablets or the extent of the problem within particular batches. Additionally, the FDA noted Caraco's failure to thoroughly investigate unexplained discrepancies in the manufacture of its drugs, including the releasing of lots for distribution to consumers despite knowledge of tablet defects in earlier lots, as well as the failure to establish or follow standard operating procedures with regard to the examination of drugs while in the process of manufacturing or the responsibilities and procedures applicable to Caraco's quality control unit.

b. In a March 31, 2008, letter signed by Defendant Movens, Caraco responded to the Form 483. This letter revealed significant violations of cGMP at Caraco, particularly with regard to manufacturing drug tablets of the specified size and dosage. Nevertheless, defendant Movens stated at the outset of the letter that:

> Caraco continues to strive for excellence in our day to day compliance objectives and continues to improve our corrective and preventative action plans. We review areas on a routine basis both internally and by outside auditing firms in order the evaluate risks within our company or any non-compliance. Caraco continues to be compliant in all areas of operations. We believe these observations do not necessarily reflect systemic failures, but are the result of individual human error.

The letter continued by, once again, representing that Caraco had or would issue revised procedures and practices to address the FDA's concerns. With regard to the FDA's observations regarding the failure to follow already established procedure, defendant Movens again characterized these failures as either an "isolated instance" that did not reflect Caraco's "normal investigation practices" or "an isolated instance of human error by one individual." Despite Caraco's and Movens's representations that Caraco would immediately correct these significant cGMP violations, these violations continued.

A. The May 2008 FDA Inspection

60. At the start of the Class Period, from May 1, 2008 through June 11, 2008, the FDA conducted a cGMP inspection of Caraco's Elijah McCoy manufacturing facility, the first full FDA cGMP inspection of Caraco's facilities since 2006. On June 11, 2008, the FDA issued a Form FDA 483 to Caraco, addressed to defendant Movens, listing fourteen observations regarding Caraco's manufacturing practices. Many of these observations and concerned failures in fundamental operating procedures regarding the manufacture of drugs for human consumption. Moreover, the overarching theme therein was the Company's inability to produce quality pills, *i.e.*, drug products that have the identity, strength, quality, and purity they purport or are represented to possess. These observations included:

a. Failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed (*e.g.*, the failure to fully investigate incidents of contaminated, adulterated or out-of-specification drugs or raw materials);

b. Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other drug products that may have been associated with the specific failure or discrepancy [*e.g.*, investigation of product cross contamination did not extend to all other drug lots dispensed during the same time period];

c. There are no written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess;

d. The responsibilities and procedures applicable to the quality control unit are not fully followed;

e. Component weighing, measuring, and subdividing operations are not adequately supervised;

f. Records fail to include an individual inventory record of each component and reconciliation of the use of each component with sufficient information to allow determination of any associated batch or lot of drug product [*e.g.*, the company adjusted raw material inventory amounts without investigating where extra material came from or which drug batches or lots it was used to make];

g. Batch production and control records did not include complete information relating to the production and control of each batch;

h. Equipment and utensils are not cleaned and maintained at appropriate intervals and prevent malfunction and contamination that would alter the safety, identity, strength, quality, or purity of the drug product;

i. Written production and process control procedures are not documented at the time of performance;

j. Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions;

k. cGMP training is not conducted on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them;

l. Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance;

m. Procedures describing the warehousing of drug products are not established; and

n. For components removed from the original containers, the new container fails to be identified with receiving or control number.

61. The magnitude and extent of Caraco's cGMP deficiencies listed in the June 11, 2008, Form 483 was so substantial, that it prompted Defendant Movens to send a letter on June 19, 2008, to initially respond to the observations, and letting the FDA know that while the Company would certainly be providing a detailed response and corrective action plan to the FDA on or prior to July 11, 2008, that Caraco and Defendant Movens "take the FDA observations from the GMP inspection initiated on May 1, 2008 very seriously" and noted that the Company considered all observations "critical." Therein, Defendant Movens stated:

> I wanted to send an initial response letter to you to explain that Caraco management is committed to making quality system improvements in order to meet full compliance with the GMP regulations. Caraco considers this the top priority for the company and is committed to providing the necessary resources to accomplish our compliance initiatives expeditiously and effectively. We take the FDA observations from the GMP inspection initiated on May 1, 2008 very seriously and are already identifying and implementing corrective action plans. These corrective actions will not only address the specific findings on the FDA Form 483 but also will address other improvements to Caraco's quality systems and processes. As part of our corrective action plan we will make improvements to our management review process and provide increased Quality Assurance oversight to strengthen our quality system. Caraco management will monitor the effectiveness of these quality system improvements and make adjustments as indicated.

62. On July 10, 2008, Caraco responded to the June 11, 2008, Form FDA 483 by letter signed by defendant Movens. In the response, Movens again committed to take steps to both correct the deficiencies, and to make comprehensive systematic corrections to standard operating procedures to help assure that similar violations would not occur in the future. He again promised to take corrective actions including, but not limited to, the following: organizational changes; commitment to complete and close all delinquent incident reports; training; hiring of consultants; revision to standard operating procedures, process parameters, and quality attribute specifications; and revision to the material system.

63. Thereafter, Movens again wrote to the FDA District Director, Joanne Givens, on July 25, 2008, to update "the remaining compliance projects associated with the May 2008 FDA inspection." The letter marked the first of Caraco's "bi-weekly updates" to the FDA about its efforts to address its compliance deficiencies. Therein, Movens not only thanked her for meeting with him the prior week to discuss Caraco's "efforts to improve compliance," but also stated:

> As I have conveyed previously we are looking at global improvements and are taking a holistic approach in our improvement plan. We have dedicated Quality

> Assurance Auditors to specific GMP areas, such as dispensing and the various manufacturing areas. In addition, our manufacturing supervisory staff is being supplemented in all areas as needed.

64. On August 8, 2008, Defendant Movens sent his second "bi-weekly update" to the FDA on "the remaining compliance projects associated with [Caraco's] May 2008 FDA inspection" and noted that Caraco "had completed four action items since our last correspondence and have two remaining."

65. Again on August 22, 2008, Defendant Movens sent another "bi-weekly update" to the FDA, indicating that Caraco was "on target to complete the final two items."

66. Again on September 5, 2008, Defendant Movens sent another "bi-weekly update" to the FDA, again indicating that Caraco was "on target to complete the final two items."

67. Again on September 19, 2008, Defendant Movens sent another "bi-weekly update" to the FDA, again indicating that Caraco in addition to the final two items to its Action Plan, the Company had added another item to be tracked into the Action Plan.

68. Again on October 3, 2008, Defendant Movens sent another "bi-weekly update" to the FDA, and indicated Defendant Movens would "continue to provide you with a final update on Caraco's progress in the next report" and that "the next report will be sent on October 24, 2008 which will mark our completion of all activities listed in our Action Plan."

69. Again on October 3, 2008, Defendant Movens sent the final "bi-weekly update" to the FDA, and again expressly demonstrated the Company's "sense of urgency" in responding to the FDA's June 2008 Form 483.

B. On October 31, 2008, the FDA Issues a Warning Letter to Caraco

70. On October 31, 2008, the FDA sent a Warning Letter, 2008 DT 05, by certified mail, return receipt requested, to defendant Movens as chief executive officer of Caraco (the "Warning Letter"). In the Letter, the FDA notified Caraco that its May 1, 2008 to June 11, 2008 inspection of Caraco's manufacturing facilities revealed "significant deviations from current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals (Title 21, *Code of Federal Regulations*, Parts 210 and 211)" which "were listed on a List of Inspectional Observations (FDA-483) form issued to you at the close of the inspection." The FDA concluded that "[t]hese CGMP deviations cause the drug products being manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) [21 U.S.C. § 351(a)(2)(B)] of the Federal Food, Drug, and Cosmetic Act (the Act) in that the manufacture, processing, and holding of drugs does not conform with CGMP to assure that such drugs meet the requirements of the Act as to safety, and have the identity and strength and meet the quality and purity characteristics that they purport or are represented to possess."

71. The Warning Letter further discussed a number of observations from the June 11, 2008 Form FDA 483 and noted the inadequacy of Caraco's response to these observations. In particular, the FDA noted that a number of the violations discussed in the June 11, 2008 Form FDA 483 were repeat violations from the previous inspections in 2005, 2006 and March 2008 and that the firm's internal and external audit procedures apparently had failed to identify the lack of cGMP compliance outside of the FDA inspection process. The Warning Letter focused on, but was not limited to, six observations including: (1) failure of the Quality Control Unit (QCU) (a) to review and approve all drug product production and control records to determine

compliance with all established, approved written procedures before a batch is released or distributed, and (b) to thoroughly investigate a batch or any of its components not meeting any of its specifications and extend investigations to other batches of the same drug product and other drug products that may have been associated with the specific failure [21 CFR § 211.192] [a repeat violation of the 2005, 2006 and March 2008 inspections]; (2) failure of the QCU to follow written procedures [21 CFR § 211.22(d)][a repeat violation of the 2006 and March 2008 inspections]; (3) failure of the QCU to approve or reject all procedures or specifications impacting the identity, strength, quality, and purity of the drug product [21 CFR § 211.22(c)]; (4) failure to maintain component records that include reconciliation of the use of each component with sufficient information to allow determination of any batch or lot of drug product associated with the use of each component [21CFR§ 211.184(c)]; (5) failure of the appropriate organizational unit and the QCU to review and approve any changes to established written procedures [21 CFR § 211.100(a)]; (6) failure to establish valid in-process specifications derived from previous acceptable process average and process variability estimates where possible [21 CFR § 211.11 0(b)]; and (7) failure to maintain equipment at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements [21 CFR §211.67(a)][repeat observation of 2005 inspection].

72. After discussing these observations, the FDA added that "[W]e have serious concerns regarding: a) your firm's compliance history including several past inspections that documented significant CGMP deficiencies, b) the serious nature of the observed violations, c)

your plans for expansion under these violative conditions, and d) the risk to consumers associated with the CGMP deviations involving potential product contamination."

73. The Warning Letter closed by stating:

> The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of the CGMP regulations and with the Act.
>
> You should take prompt action to correct deficiencies at your facility. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts. Additionally, FDA may withhold approval of requests for export certificates, or approval of pending new drug applications listing-your facility as a manufacturer until the above violations are corrected. A reinspection may be necessary.

74. On November 24, 2008, defendant Movens responded on behalf of Caraco to the October 31, 2008 Warning Letter. In his response, Movens stated that "[w]e recognize the seriousness of the violations and we would like to confirm that we have taken appropriate actions to correct the deficiencies in order to ensure compliance with the regulations." In the response Movens set forth actions which Caraco represented would "alleviate the agency's concerns regarding the company's compliance history, the serious nature of the observed violations and the risk to consumers." In its response, the company admitted to the inadequacy of a number of its procedures including, but not limited to, failure to assess product quality impact on other drug lots, failure to conduct appropriate quality impact analysis before granting investigation extensions, failure to fully investigate possible contamination of drug products by including source and extent of potential contamination, failure to follow standard operating procedures to assure prompt follow up and completion of investigations, test methods inadequate to identify

cross-contaminated products, failure of contamination investigations to extend to other possibly affected drug lots, lack of adequate operating procedures to prevent cross-contamination of materials during the dispensing process and lack of adequate operating procedures with regard to maintaining records capable of determining the batch or lot of drug product associated with component materials.

C. FDA Scrutiny Further Intensifies Following the Warning Letter

75. On December 11th through December 22nd, 2008, the FDA conducted a GMP/pre-approval inspection of Caraco's Farmington Hills, Michigan packaging facility. This location served as the packager for Caraco's Detroit manufacturing facility. On December 22, 2008, the FDA issued a Form FDA 483 regarding the Farmington Hills packaging facility. The Form FDA 483 contained five observations, including:

a. The inspection of the packaging facilities immediately before use is not done to assure that all drug products have been removed from previous operations;

b. The responsibilities and procedures applicable to the quality control unit are not fully followed;

c. Batch production and control records do not include information relating to the production and control of each batch;

d. The persons performing and double-checking the cleaning and maintenance are not dating and signing or initializing the equipment cleaning and use log; and

e. Written records of major equipment cleaning, maintenance, and use are not included in individual equipment logs.

76. On December 22, 2008, Ms. Putz on behalf of the FDA acknowledged receipt of defendant Movens November 24, 2008 response to Warning Letter 2008-DT-05. In that letter, Ms. Putz noted:

> I would like to reiterate a concern that we discussed during our phone call [on December 4, 2008]. There is a real problem regarding your processes that are yielding tablets of varying sizes. The fact that...there are ***a number of customer complaints regarding tablet size*** for a ***variety of products*** is disconcerting. Validated processes should yield product of consistent quality. ***This issue needs to be resolved as it has been going on the quite some time***.

(Emphasis added).

77. On January 21, 2009, defendant Movens on behalf of Caraco responded to the December 22, 2008 Form FDA 483 regarding the Farmington Hills packaging facility. As on previous occasions, the response contained a detailed point-by-point discussion of the observations in the Form FDA 483. In the response, Movens once again represented that the company was taking immediate steps to correct the systems that caused the lapses noted in the Form FDA 483. As part of the response, defendant Movens admitted that, "[f]rom the inspection, it is clear that we must still take positive steps to enhance our quality systems, primarily in the area of employee training and supervision."

78. On February 11, 2009, Caraco provided the FDA with two Field Alert Notifications regarding its Metoprolol Tartrate Tablets for two different dosages. Both indicated that "a market complaint" was received on "January 28, 2009 indicating that tablets of different sizes were found in" certain lots.

79. In a letter to the FDA dated February 19, 2009, Defendant Movens indicated additional steps the Company was taking to since submitting its response to the Form 483 observations and the Warning Letter. Most significantly, Defendant Movens indicated:

> ***We have stopped most of our internal research and development activities to allow the R&D team to act as additional support for tech services. They are analyzing the trends for recurring product anomalies and are taking appropriate action as necessary to eliminate any remaining issues with product quality. This is planned over [redacted by the FDA] which started just over two weeks ago***.
>
> * * *
>
> We have . . . tablet sorters that are being qualified this week that will become part of our online control process. We believe this will help us analyze size variation, if any, of products being produced and the positive impact of our automated machines.
>
> * * *
>
> We realize the importance of our corrective actions and the seriousness of your concerns.
>
> (Emphasis added).

80. On March 11, 2009, the FDA commenced another inspection of Caraco's Detroit manufacturing facility. This inspection continued until May 12, 2009. On May 12, 2009, the FDA issued a Form FDA 483 to defendant Movens on behalf of Caraco containing eighteen observations. Despite defendant Movens's repeated assurances of cooperation and the immediate implementation of corrective measures as set forth above over a period of time extending back to 2005, and despite the October 11, 2008 Warning Letter, the observations again concerned fundamental failures in operating procedures including a number of repeat observations from earlier inspections. These observations included:

a. Records fail to include an individual inventory record of each reconciliation of the use of each component with sufficient information to allow determination of any associated batch or lot of drug product;

b. Written procedures are not followed for the storage and handling of components;

c. A failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed;

d. Failure of written procedures to describe in sufficient detail the receipt, identification, storage, and handling of components;

e. The failure to establish control procedures to monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and the drug product, particularly thick, soft, thin, broken and imperfect appearance tablets;

f. Failure to follow written production and process control procedures in the execution of production and process control functions;

g. Failure to include weights and measures of components used in the course of processing drug product batches;

h. Failure to establish time limits when appropriate for the completion of each production phase to assure the quality of the drug product;

i. Failure to justify deviations from written production and process control procedures;

j. Failure to write and fully follow the responsibilities and procedures applicable to the quality control unit;

k. Failure to extend investigation of an unexplained discrepancies to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy;

l. Failure to assure that individuals responsible for supervising the processing of a drug product have the training and experience to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess;

m. Failure of written records of investigations of drug complaints to include the findings of the investigation and the follow-up, including investigations relating to numerous size and weight variations in drug tablets over a variety of products;

n. Failure to maintain records so that the data can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures;

o. The lack of enough adequate space for the orderly placement of equipment and materials to prevent mix-ups and contamination between different components and in-process materials;

p. Failure of equipment used in the manufacture, processing, packing or holding of drugs to have appropriate design to facilitate operations for its intended use; and

q. Failure of written procedures for cleaning and maintenance to include parameters relevant to the operation.

81. On March 20, 2009, Caraco provided the FDA with a Field Alert Notification regarding its Digoxin Tablets, indicating that it was discovered that at least one lot contained "thick tablets" and that the Company was investigating the thick tablet issue.

82. Thereafter, on March 31, 2009, Caraco announced a nationwide "voluntary recall" of all lots of Digoxin tablets "due to size variability." The Company explained that "the tablets are being recalled because they may differ in size and therefore could have more or less of the active ingredient, digoxin" and that all the recalled tablets were "manufactured by" Caraco.

83. On April 17, 2009, Caraco provided the FDA with a Field Alert Notification regarding its Citalopram tablets, indicating that with regard to at least one lot, it was "observed that tablets varied in weight" and that Caraco "is actively investigating the variation in tablet weight."

84. On April 17, 2009, Caraco initiated a recall of certain products. According to FDA documents regarding the recall, the reason for the recall was "some of the tablets being oversized or undersized, which will result in the patient not receiving the expected dose." The FDA documentation on the recall lists the recall as being "FDA Initiated." The FDA documents further indicate that the products were manufactured from "3/30/2008 To 12/08/2008" and that they were distributed from "04/24/2008 To 01/28/2009." The products listed in the FDA recall documents are 2,138 bottles containing 1,000 tablets of "Clonazepam Tablets, USP, 0.5 mg," 80,055 bottles containing 1,000 tablets of "Metoprolol Tartrate Tablets, USP, 25 mg," and 4,330 bottles containing 1000 tablets of "Metoprolol Tartrate Tablets, USP, 50 mg."

85. Also on April 17, 2009, the Company recalled an additional 410,033 bottles of tablets covering 29 products. According to the FDA recall documents, the "Public Reason for Recall" was "Lack of assurance products do not contain an additional drug ingredient." The recall information further identifies the "Complete Reason for Recall" as "During an FDA inspection, it was determined that the firm was unable to account for all of its digoxin raw material, and the firm elected to recall all products manufactured since the raw material went missing. The firm reports they analyzed retain samples of all lots for digoxin and all results were negative." Moreover, it identifies the recall as being "FDA initiated."

86. On June 8, 2009, the Company conducted a recall of 449 bottles containing 500 Citalopram Hydrobromide Tablets, USP, 10 mg, which according to the FDA recall documents had been manufactured from "9/30/2008 To 10/16/2008. Further, according to the documents, the "Public Reason for the Recall" as "some of the tablets are oversized or undersized, which will result in the patient not receiving the expected dose." The documents further indicate that the recall was "FDA Initiated" and provides that the "Complete Reason for Recall" as

> [Caraco] submitted an NDA field alert dated 4/17/09 stating that the tablet weight tolerances are [redacted] mg, but that some tablets in this lot may weight as little as [redacted]mg and some may weigh as much as [redacted]mg. The problem was not seen during production, but was discovered during stability testing. After discussion with FDA that this represents a potential health hazard, the firm decided to recall.

87. On June 19, 2009, defendant Movens on behalf of Caraco responded to the May 12, 2009 Form FDA 483. The response claimed that the company "completely understood the serious nature of the observations" and had taken "the corrective actions necessary to gain further compliance, including changing leadership in various critical areas of the company, purchasing a new tableting machine, tightening process parameters and aligning product with

appropriate machinery. Caraco further represented that its Quality Management System, designed to track all functional aspects of the quality system, was in the final stage of validation and would "eliminate gaps and implement corrective actions when gaps are noted for any of our quality systems." Movens further stated Caraco's belief that "all products on the market have been tested for their efficacy and there are not safety concerns." The response, as before, included a detailed point-by-point response to each of the observations noted in May 12, 2009 Form FDA 483 which set forth Caraco's explanation of the discrepancies observed by the FDA, any corrective measures the company had adopted or intended to adopt and any disputes with inspectors' observations. This letter revealed that Caraco was continuing to significantly violate cGMP despite its representations of corrective action.

88. In the June 19, 2009 response to the FDA, Defendant Movens and Caraco acknowledged the existence of the Company's continuing problem with "reoccurring variability product issues," *i.e.*, Caraco's inability to consistently manufacture pills that were the right size and weight. In the letter, Defendant Movens stated:

> For our product variability concerns which resulted in past recalls and product complaints of products, we have taken a [redacted] approach of matching up [redacted]. We have tightened our operational ranges by reviewing our historical critical product parameters in order to optimize our performance for a quality output within the regulatory guidelines. Certain product like:
>
> • Metoprolol which was representative of approximately [redacted] of our variability issue has been validated on a new [redacted] tabletting machine prior to January and since then we have not had any issue or concerns with this product. In essence the product is married to the right machine. No changes were required based upon our original filing.
>
> • Clonazepam which was approximately [redacted] of variability concern has been produced with a tightened operational range and consistent particle size through consistent [redacted] rates which has allowed us to eliminate any variability.

> • Digoxin which represents [redacted] of the variability problem of reoccurring products is under the same process and we anticipate we will have the same outcome, since results to date are encouraging.
>
> • Metformin which was also part of our variability study [redacted] but did not face any complaints in the review period was corrected earlier by tightening process parameters along with aligning this product with the appropriate machinery.
>
> ***This corrective action, born out of our variability study, established in November 2008***, effectively resolves our reoccurring variability product issues.
>
> * * *
>
> With deliberate efforts, since December 15, 2009, we have slowed down new product development and technology transfer activities for continuous focus on cross-functional training and resolution of process and product related discrepancies. Our R&D team is actively participating in conducting in process reviews, investigations, providing additional support in process validations, technical training, conducting audits, revising batch records, and other areas of expertise to assure proper functioning of compliance and technical systems.

(Emphasis added).

VII. CONFIDENTIAL WITNESSES CONFIRM THAT DURING THE CLASS PERIOD, CONTRARY TO DEFENDANTS' PUBLIC REPRESENTATIONS AND UNBEKNOWNST TO THE PUBLIC, CARACO'S REMARKABLE GROWTH WAS DRIVEN BY A RECKLESS AND MYOPIC FOCUS ON PRODUCTION VOLUME AT THE EXPENSE OF PRODUCT QUALITY AND REGULATORY COMPLIANCE, AND THAT CARACO WAS PLAGUED BY SYSTEMIC MANUFACTURING AND QUALITY CONTROL AND ASSURANCE FAILURES

89. Plaintiffs' investigators interviewed the following former Caraco employees from before, during, and after the Class Period and obtained the following information.

90. Confidential Witness 1 ("CW1") was a Manufacturing Manager at Caraco from September 2008 to July 2009. CW1's duties were in dispensing. CW1 stated that Caraco's senior management hired him/her and others to address Caraco's history of problems. CW1 has over 25 years of experience working in the pharmaceutical industry.

a. According to CW1, when he/she arrived at Caraco many of the procedures were not up to date and were inconsistent with current Good Manufacturing Practices.

b. CW1 also indicated that Caraco had an insufficient material resource planning ("MRP") system. The system, simply called "ERP," was internally cobbled together by Sun Pharma. According to CW1, the ERP system was so difficult to use that it was nearly impossible to train employees to use it properly. Naturally, Caraco's inadequately trained employees were unable to use the ERP system to fully record movements of raw materials as they occurred in the dispensing area. Senior employees were then forced to make these entries into the system ***after*** they happened based on logs that operators were supposed to complete. Despite having a BS degree in Chemistry, CW1 admitted that it was hard for him/her to figure out the ERP system.

c. CW1 was involved with the May 2009 FDA audit. The FDA personnel who conducted the audit were concerned that Caraco could not account for some missing inventory. They also disapproved of the ERP system. Additionally, the FDA was particularly concerned that the changes that senior management had previous told the FDA would be made had not been properly implemented. Specifically, Caraco had told the FDA that they would put a bar coding system in place. But, according to CW1, Caraco was trying to develop a system in-house instead of buying an off the shelf product – just as it had with the insufficient ERP system. The system was not fully implemented during CW1's employment, but based on his/her initial experience, the system was very hard to use – only the people who had written the software could understand how to use it. According to CW1, it was important to fully record movements of raw materials as

they occurred in the dispensing area. But operators were not trained or allowed to enter these "transactions." As a result, senior people such as himself/herself were required to make the entries, long after they had happened, based on logs that operators were supposed to complete. But even CW1, who holds a Chemistry Degree, found it difficult to understand and use the ERP system.

d. According to CW1, most of the problems at Caraco were in the tablet compression area. There were also problems with the Adverse Drug Experience, or "ADE," reports. According to CW1, ADE reports were filed with the FDA belatedly, as the two employees who filed the Adverse Drug Experience reports were occupied by their customer service duties, taking phone calls and emails from customers, pharmacies, and distributors.

91. Confidential Witness 2 ("CW2") was a Dispensing Supervisor at Caraco's headquarters at Elijah McCoy Drive, Detroit from February 2008 to September 2008. From then until July 2009 he/she worked in Caraco's Farmington, Michigan packaging operations.

a. CW2 described the utter lack of proper manufacturing practices and quality assurance at Caraco. For example, CW2 noted that standard operating procedures, or "SOP," were changed ***every day***. Yet, the Senior Packaging Manager who was making and overseeing these changes, and the Associate Director of Manufacturing to whom he/she reported, both "had no clue" on what they were doing. They were trying to install a complicated scanner-based electronic tracking system in place – even though they could not even get the pills properly in the bottles.

b. CW2 further indicated that Caraco employed a "fixer." CW2 said that if there was a problem with the raw materials numbers, for example, this employee would adjust the numbers and "fix it."

c. According to CW2, problems with pill strength were endemic. In dispensing, Caraco was getting the strength of pills wrong. For example, despite each component in a pill requiring precise weight measurements down to 1/1000 of a gram, employees "had the weights completely out of whack."

d. According to CW2, management failed to significantly respond to the problems. Rather, management "scratched their heads" and decided to retrain employees on the SOP. CW2 said that this wouldn't help because the SOP was literally changing every day. The result was that people on the floor were simply confused.

e. According to CW2, ADE reports were consistently delayed. Complaints would come in through customer service from a pharmacy or a customer. Examples of problems included insufficient pills in the bottle, broken pills, or a bad reaction to the drug. However, complaints were written up and sent to Quality Assurance. Quality Assurance would review the problem with the originating department and, after a delay in which Caraco management would protect themselves, Caraco would finally file a report.

f. CW2 was indirectly involved with the December 2008 FDA audits. The FDA's largest problem was that Caraco had not fixed the problems that it had said it would fix. That is, Caraco had failed to address properly the issues that the FDA had identified in the Form 483. It seemed to CW2 that management "kind of blew it off."

g. According to CW2, the Company was trying to make too many drugs at the same time. Indeed, CW2 stated that the whole company was run "by the seat of the pants."

92. Confidential Witness 3 ("CW3") was a chemist for Caraco from January 2007 to October 2008. According to CW3, Caraco had "many infractions." It was a "huge production failure" due to the intense pressure to make more drugs despite the lack of infrastructure to do so. For example, according to CW3, an employee would blend the ingredients, then test the mixture to make sure it was correct; but production would consistently start making tablets ***before*** the tests were complete. If a problem was found later, the machine operators were blamed.

93. Confidential Witness 4 ("CW4") and Confidential Witness 5 ("CW5") were Senior Manufacturing Managers at Caraco from July 2008 until July 2009. CW4 and CW5 officially reported to Robert Wood, Associate Director of Manufacturing, who reported to Kaushik Gandhi, Vice President Manufacturing, who in turn, reported to Defendant Movens. However, both CW4 and CW5 communicated directly with Movens throughout their employment.

a. CW4 confirmed the rampant manufacturing problems at Caraco. He/she stated that in 2008 alone, there were over ***1,000*** incidents of problems, for example weight variation, contaminants such as hair found in the product, or tablets that were too thick/thin. Indeed, CW4 stated that he/she had seen more hair contamination problems in a week than he/she had seen in all of his/her combined 40 years in manufacturing.

b. CW5 also confirmed that there were serious, rampant problems with tablet variation. CW5 noted that tablet variation was a serious problem, as Digoxin, for

example, was a Class 2 drug that could be lethal at the wrong dosage. CW5 noted that in one set of tests weighing over 900,000 tablets, approximately 2% were found to be of the wrong size – an incredibly high ratio of defective product for pharmaceuticals. Indeed, when CW5 first arrived, Caraco was "like the wild west."

c. During their time at Caraco, both CW4 and CW5 discussed the machines used to make tablets directly with Defendant Movens. CW4 told Movens that the "Sejong" tablet press machines Caraco was using were not proper for producing a pharmaceutical grade product. CW5 specifically told Movens that the Company needed better compression machines in order to reduce tablet production problems, including the too thick/thin problems. Both CW4 and 5 advised Movens to buy "Korsh" machines to make tablets and Movens initially promised that the Company would buy them. Later, Movens likened a Korsh machine to a Cadillac and stated that he would rather have a Buick (referring to the Sejong machines). CW4 replied to Movens that he/she "would be happy with a Buick but what we have here are Yugos."

d. In addition, CW4 stated that even if a product did not meet the in-house specifications, the manufacturing people would release it anyway. According to CW4, the problem stemmed from the attitude of management to "get the tablets out the door." Machines were not allowed to be shut down even when updating SOPs. CW5 corroborated this account, stating that Kaushik Gandhi ordered continued production without interruption – even during SOP revisions.

e. CW4 also described Caraco's lackadaisical response to FDA concerns. During one FDA inspection, for example, the FDA discovered that Caraco could not

account for approximately 1.3 kilograms of Digoxin – a Class 2 drug that could be lethal at the wrong dosage. According to CW4, the FDA was concerned that the Company did not do a thorough investigation because the missing Digoxin could have been mixed in with other drugs and dangerously released into the market. Instead of conducting a thorough investigation and checking other products, initially the Company only looked at surveillance videos and searched the warehouse before arriving at the assumption that the missing Digoxin had been accidentally thrown out.

f. CW4 indicated that Movens was personally involved with operations and FDA interactions, especially after and FDA observation noted that Movens did not know what was occurring at his own plants.

g. CW5 also described Movens's intimate knowledge of the rampant problems at Caraco. CW5 attended meetings to address the manufacturing problems at the Company. According to CW5, Movens and several other persons would also attend these meetings, including CW4 who attended the meetings occasionally. Indeed, CW4 confirmed the existence and his/her attendance at some of these meetings. CW5 recalled a Sun Pharma Vice President of Quality attending at least once. While the meetings were first held once a week, they were subsequently held ***once or twice per day***, Monday through Friday at 10 a.m. or 5 p.m., or both. The meetings were held in a conference room at the Elijah McCoy facility in Detroit adjacent to Movens's office.

h. CW5 also stated that in or around December 2008, Sun Pharma installed two senior managers at Caraco: Sandeep Mehta as Director of Manufacturing and Sunil

Ajmera as Vice President of Manufacturing. Mehta and Ajmera both pushed for production "over anything else."

i. According to CW5, both Mehta and Ajmera ostensibly reported directly to Movens. However, corroborating CW8's account, it appeared that Mehta and Ajmera, as agents of Sun Pharma, were running Caraco. CW5 stated that when he/she and CW4 approached Movens because it was impossible to meet Mehta's and Ajmera's demands for continued production while developing new SOPs every day, Movens replied that ***"his hands were tied" because he reported to Sun Pharma.***

j. Mehta's and Ajmera's control over Caraco's operations and push for production at the expense of regulatory compliance was undeniable. CW5 stated that in March 2009, he/she shut down one of the machines and rejected the machine's product. He/she was then called over and told directly by Mehta and Ajmera to ***not*** reject anything. Ajmera then directed the Quality Assurance director to put the machine back into operation and to accept the machine's product. The FDA subsequently questioned these actions.

k. CW5 described another incident demonstrating Mehta's and Ajmera's control over Caraco's operations and continued push for production at the expense of regulatory compliance. CW5 rejected a certain drug product due to weight problems. Ajmera indicated that the Company would open up the drug capsules, reclaim the ingredients, and re-make the drug capsules, despite the fact that the SOPs forbade the reclamation of drug product in this manner.

l. CW5 stated that he/she was hired by Caraco to "fix everything." Upon his/her arrival at Caraco, CW5 immediately faced over 1,000 SOPs that needed to be updated. In some cases, the SOPs had not been updated in 12 to 14 years.

94. Confidential Witness 6 ("CW6") was a compression supervisor between December 2007 and July of 2009. Prior to working at Caraco, he/she had worked at another pharmaceutical company for 17 years. CW6 had direct communications with Defendant Movens.

a. As soon as CW6 started, he/she saw things that were "totally wrong." CW6 was concerned about the quality of the product and noted that the set up in the compression stage of manufacturing was incorrect and resulted in metal shavings getting into the product. He/she tried to rectify the problem with management but the ethic was "more about pushing production than quality." According to CW6, every time there was an issue, management wanted to bypass the issue so that they could get production.

b. Corroborating CW4 and CW5's testimonies, CW6 noted that the Sejong machines being used for large production were causing problems because these machines were designed to be used for making small lots of vitamins, not large quantities of pharmaceutical grade drug products. CW6 further noted the problem with the Company's inadequate SOPs.

c. CW6, corroborating CW4 and CW5's testimonies, also attended some of the quality review meetings that Defendant Movens held and attended. Manufacturing problems, such as the tablet variations, were discussed.

d. Also corroborating CW4, CW5, and CW8's testimonies, CW6 stated that he met resistance from Sunil Ajmera and Sandeep Mehta when protesting that the wrong adapters were being used with the scales.

95. Confidential Witness 7 ("CW7") was a Manufacturing Supervisor from March 2008 through September 2009. He/she came over to Caraco from another pharmaceutical manufacturer.

a. When he/she interviewed with the Company, he/she was "amazed how things were running." CW7 recalled telling Kaushik Gandhi that had the FDA come right then, they would have shut down the company.

b. CW7 stated that the problems at Caraco were rampant: raw materials, blending, compressing, dispensing, the use of Sejong machines designed for vitamins and not pharmaceuticals. CW7 wanted new machines but was told by Mehta and/or Ajmera that that wasn't going to happen.

c. Around January or February 2009, CW7 had a quality issue with foreign matter being found during blending. He/she followed the SOP and called Quality Assurance who told him/her to just continue production and do nothing even though the operator had found 2 bits of paint and a small piece of fiber in the middle of the blending process. No incident report was filed as a result, an example of an occurrence that happened 10's of times. Even though there were lots of issues, according to CW7, most of them were not documented.

d. CW7 corroborated CW4, CW5, CW6 and CW8's statements that Sunil Ajmera and Sandeep Mehta – the two senior managers installed at Caraco by Sun Pharma

– exercised broad control over Caraco's operations. Indeed, CW7 viewed Ajmera and Mehta's installation at Caraco as "a reorganization" by Sun Pharma. According to CW7, "Sunil and Sandeep were running the show."

96. Confidential Witness 8 ("CW8") was a Quality Assurance Technical Manager at Caraco from September 1992 through July 2009. CW8 was one of the original 30 employees of the Company. His/her duties included calibration, destruction of controlled substances, quality investigations, addressing quality issues with vendors, checking the water system, and the testing control systems. CW8 reported directly to the Director of Quality Assurance, Dan Barone, and Barone's predecessor, George Marshall, prior to December 2003.

a. CW8 stated that the tablet compression problem of producing tablets too thick or too thin was so rampant that it was common knowledge within the Company. Thus, CW8 stated that Movens must have known about the tablet compression problem.

b. CW8 further stated that a quality review board was assembled to discuss quality issues. He/she stated that the quality review board met once a week, that Movens and Barone attended these meetings, among others. He/she indicated that the tablet compression problem creating too thick/thin tablets, and the complaints caused by the problem, were discussed at these meetings.

c. CW8 corroborated that Movens seemed to not always be in control over Caraco's operations, especially after Sun Pharma installed Sunil Ajmera and Sandeep Mehta at Caraco.

97. Confidential Witness 9 ("CW9") was a Production Supervisor at Caraco from March 2007 through June 2008. In packaging, CW9 worked side-by-side with Caraco's quality inspectors.

a. CW9 confirmed that he/she and the quality inspectors frequently discovered tablets that were too thick/thin, as well as tablets that were broken and/or chipped. CW9 indicated that the problem occurred throughout his/her employment at Caraco.

b. CW9 indicated that incident reports regarding tablet problems were eventually funneled upward to Dan Barone.

98. CW10 was a Vice President of Caraco from 1999 and there until January 2009. Prior to Caraco, he/she was a general manager for two operating plants of Sun Pharma.

a. According to CW10, between 2006 and 2008 there would be two separate meetings that were held. There were quality review board meetings and operations meetings. CW10 stated that Defendant Movens gave instructions to all senior management and managers in general in operations and quality that any issues directed at quality would be directed to him first. As a result, CW10 indicated that in some cases, Daniel Barone, the Director of Quality, would find out about quality issues second as Defendant Movens would find out first.

b. CW10 indicated that while From 7 A.M. to 8 P.M., CW10 reported directly to Defendant Movens, after 9 P.M., however, CW10 received calls from India. On a regular basis, CW10 would have conversations with Sunil Valia, the

Wholetime Director of Sun Pharma, who reported to Defendant Shanghvi, the Chairman of both Caraco and Sun Pharma. Sometimes, CW10 would speak directly with Defendant Shanghvi. During conversations with Valia, CW10 would brief Valia on the status of operations at Caraco and targeted goals for production would be assigned. Over the course of years, production was moved up as they hit certain goals. First from 10 lots per month to 40 lots per month. Then from 40 to 80 lots per month. Once they hit 60 lots per month though they were assigned 100 lots per month. When they got to 100 they were given 150 lots per month. CW10 indicated that they achieved 150 lots per month and were given 180. While they never achieved 180 lots per month and only got to 160, they were assigned 240, but that was at the time CW10 left the Company and they were stuck at 160.

VIII. DEFENDANTS ISSUED MATERIALLY FALSE AND MISLEADING STATEMENTS WITH SCIENTER DURING THE CLASS PERIOD

99. Caraco and the Individual Defendants artificially inflated the price of Caraco's stock by issuing materially false and/or misleading statements during the Class Period, including press releases, Form 10-Q quarterly reports, and a Form 10-K annual report filed with the SEC, as set forth below.

100. The Class Period begins on May 29, 2008. On this day, Caraco issued a press release entitled, "Caraco Pharmaceutical Laboratories, Ltd. Reports Record Results for the Fourth Quarter and Fiscal Year 2008." Therein, the Company, in relevant part, stated:

> DETROIT, May 29 /PRNewswire-FirstCall/ -- Caraco Pharmaceutical Laboratories, Ltd. (Amex: CPD) posted record net sales for the fourth quarter and the year ended March 31, 2008 (Fiscal 2008), of $191.8 million and $350.4

million, respectively, as compared to $32.7 million and $117.0 million for the corresponding periods of Fiscal 2007. Net income grew to $11.5 million and $35.4 million for the fourth quarter and Fiscal 2008, respectively, as compared to net income of $9.5 million and $26.9 million during the corresponding periods of Fiscal 2007. The annual net income of $35.4 million for Fiscal 2008 was a record for the Company.

* * *

[Defendant] Movens stated,

"Our expansion of our facilities should be completed prior to the end of calendar year 2008. This manufacturing facility along with our new distribution facility which we recently leased should provide the capacity we need to supply our customers effectively. ***Our training and succession planning is being enhanced to support our growth and predict future operational efficiencies. We are working with local universities and technical schools in order to provide the proper talented employees required to perform in a highly regulated business. This should create and solidify the pool of personnel required at all levels of the company to support our growth and provide careers for the local economy. We anticipate improved productivity as our staff continues to increase their experience in their respective positions."***

"Our internal efforts, combined with Sun Pharma in developing new products have also picked up momentum and this should permit us to grow at the level of our guidance as provided below. Based on our current distribution and sale and marketing agreements with Sun Pharma and our internal portfolio of products and future approved products, we believe we will achieve 25% growth in sales for Fiscal 2009, compared to Fiscal 2008," added Mr. Movens.

"The Company intends to aggressively move forward with the development of new products. While the development of new products will increase our cash R&D expense and impact EPS, we believe that we will continue to have the cash and other means available to meet increased working capital requirements, fund anticipated Paragraph IV certification litigation legal expenses, and finance further capital investments. Product development is a critical element in meeting expectations in the future,"

(Emphasis added.)

101. The foregoing statement was materially false and/or misleading when made because it created the impression that Caraco could train, and was training, its employees to

properly grow the company in a "highly regulated business." However, Defendants knew, or were reckless in not knowing, the following:

a. That as subsequently revealed in the FDA Form 483 following the May 2008 inspection, Caraco employees engaged in the manufacture and processing of a drug product actually lacked the training required to perform their assigned functions and GMP training was not conducted by Caraco on a continuing basis and with sufficient frequency to assure that employees remained familiar with cGMP requirements applicable to them. Specifically, as an example the Form 483 indicated that "review of training records of four employees in the Dispensing Department show incomplete documentation of minimum training requirements to enable a person to perform the assigned functions."

b. Furthermore, as stated by CW1 above in ¶90(b), Caraco's poor infrastructure rendered it virtually incapable of properly training its employees to use the "ERP" system to track raw materials. CW1 also indicated that Caraco had an insufficient material resource planning ("MRP") system. The system, simply called "ERP," was internally cobbled together by Sun Pharma. According to CW1, the ERP system was so difficult to use that it was nearly impossible to train employees to use it properly. Naturally, Caraco's inadequately trained employees were unable to use the ERP system to fully record movements of raw materials as they occurred in the dispensing area. Senior employees were then forced to make these entries into the system ***after*** they happened based on logs that operators were supposed to complete. Despite having a BS

degree in Chemistry, CW1 admitted that it was hard for him/her to figure out the ERP system.

102. On June 10, 2008, Caraco filed its Annual Report with the SEC on Form 10-K for the 2008 fiscal fourth quarter and full year. The Company's 10-K was signed by Defendants Movens and Shanghvi and reaffirmed the Company's financial results previously announced on May 29, 2008. The company's statements regarding regulation and FDA compliance further noted:

> The FDA recently concluded an inspection in February 2008. This specifically addressed a follow up to a voluntary class II recall the Company performed in January 2008 on one strength of its metformin products we currently market. ***The product recall announced by the FDA was limited to a single compression machine malfunction, and affected two lots. The Company chose to recall seven lots that were produced on that particular machine as an additional safeguard***. The Company was issued a notice on Form 483. ***The Company has responded accordingly and we believe we remain substantially compliant.*** In May 2008 an investigation was initiated as part of a standard cGMP inspection and pre-approval inspection for three products. ***We continue to focus on improving the amount of support in both quality assurance and quality control***.
>
> * * *
>
> **FDA Compliance**
>
> The FDA recently concluded an inspection in February 2008. This specifically addressed a follow up to a voluntary class II recall the Company performed in January 2008 on one of the strengths of its metformin products it currently markets. ***The product recall announced by the FDA was limited to a single compression machine malfunction, and affected two lots. The Company chose to recall seven lots that were produced on that particular machine as an additional safeguard***. The Company was issued a notice on Form 483. The Company has responded accordingly and we believe we remain substantially compliant. In May 2008 an investigation was initiated as part of a standard cGMP inspection and pre-approval inspection for three products. ***We continue to focus on improving the amount of support in both quality assurance and quality control in order to continually improve our performance in quality***. This support is derived from the improvement of systems, training on risk management and cGMP, while adding the appropriate level of personnel to support our growth.

> Additionally we have invested in more automation for improved output and quality. ***During Fiscal 2008, in addition to our own internal audits we have retained outside companies to audit both the laboratory and manufacturing areas of our Company in order to improve and or maintain our systems of operation. These audits were based on a historical look back and offered improvements based on Caraco's future requirements. The audits also included follow up on recommendations of best practices made by the FDA. We continue to focus on improving the amount of support in both quality assurance and quality control in order to continually improve our performance and outcome in quality. We have focused our attention for continual improvement of our Corrective And Preventative Actions and cGMP, while adding the appropriate level of personnel to support our growth during Fiscal 2008***. Should the FDA issue any observations, the Company will respond to its observations with corrective actions immediately and effectively. Additionally we have made significant investments in production equipment with automated features which offer consistent control and ease in production.
>
> ***We remain extremely pro-active in regards to growing our business appropriately. We continue to grow the analytical staff, which is currently at 69 employees, thereby enabling the laboratory to better cope with a significantly increased workload with improved timeliness, higher quality, and increased cGMP compliance***. Several members of the lab staff attend supplemental professional training courses and conferences, which increases the laboratory's technical and cGMP proficiency. The lab facility has also undergone major upgrades, including a significant increase in working space to improve analyst efficiency and safety. Additional lab instruments and equipment have been purchased which will enable increased compliance with cGMP requirements, cut future costs by enabling in-house rather than contract analyses, and speed sample testing. Significant resources have also been spent to improve overall lab operations. ***Such expenditures demonstrate to the regulators, clients and shareholders that upper management is continually committed to adding quality individuals to the work force, providing the resources necessary to upgrade lab equipment and improve the effectiveness of lab operations and cGMP compliance***. Our manufacturing personnel are going through more rigorous training at the time of hire, and thereafter, in order to maintain our compliance and quality.

(Emphasis added).

103. The foregoing statements were materially false and/or misleading and made with scienter for the reasons stated above in ¶101. Additionally, the statements were materially false and misleading when made because Defendants knew or were reckless in not knowing:

a. While the Company's recall in January 2008 had been as a result of customer complaints about "over and undersized pills" and Defendants identified the reason for the recall as limited to a "particular machine," the over and undersized pills were actually part of a continuous problem with tablet variation before and during the Class Period:

i. As described by CW4, CW5, CW6, CW7, CW8, and CW9, the Company had a rampant problem producing tablets that were too thick or too thin. As set forth in ¶97(a), CW9 stated that throughout his/her employment from March 2007 until June 2008, quality inspectors frequently discovered tablets that were too thick/thin, as well as tablets that were broken and/or chipped. Similarly as alleged in ¶96(a), CW8 corroborated this account and indicated that problems with tablets being too thick or too thin was so rampant that it was common knowledge within the Company. Moreover, as set forth in ¶94(b), CW6 noted that the Sejong machines being used for large production were causing problems because these machines were designed to be used for making small lots of vitamins, not large quantities of pharmaceutical grade drug products. Similarly as set forth in ¶93(c) CW4 and CW5 indicated that the "Sejong" tablet press machines Caraco was using were not proper for producing a pharmaceutical grade product and CW5 indicated that the Company needed better compression machines in order to reduce tablet production problems, including the too thick/thin problems.

ii. As set forth in ¶¶168-69 below, the Company received numerous complaints from customers during the Class Period about pills manufactured by the Company that were either over or undersized.

iii. As set forth in ¶84, on April 17, 2009, Caraco initiated a recall of certain products because "some of the tablets being oversized or undersized" and according to FDA documentation the products were manufactured from "3/30/2008 To 12/08/2008" and that they were distributed from "04/24/2008 To 01/28/2009." The products listed in the FDA recall documents are 2,138 bottles containing 1,000 tablets of "Clonazepam Tablets, USP, 0.5 mg," 80,055 bottles containing 1,000 tablets of "Metoprolol Tartrate Tablets, USP, 25 mg," and 4,330 bottles containing 1000 tablets of "Metoprolol Tartrate Tablets, USP, 50 mg."

iv. As set forth in ¶88, Caraco and Defendant Movens later admitted that the Company was having "reoccurring variability product issues." Therein, the Company's June 19, 2009 letter to the FDA the Company ultimately had to establish a "variability study" in November 2008 to address the issue, and that the most significant reoccurring variability issues were occurring with the Company's Metoprolol, Clonazepam, Digoxin, and Metformin products.

v. As set forth in ¶79, the problem with the Company's "reoccurring variability product issues" were so severe that later in the Class Period, as admitted by Defendant Movens and Caraco in a February 19, 2009, letter to the FDA, "We have stopped most of our internal research and development activities to allow the R&D team to act as additional support for tech services. They are

analyzing the trends for recurring product anomalies and are taking appropriate action as necessary to eliminate any remaining issues with product quality."

vi. The subsequent seizure of ***all*** of Caraco's manufactured drug products and ingredients was the result of ongoing and pervasive manufacturing and compliance issue.

b. Contrary to the Company's assertions, Caraco had not responded accordingly, was not "substantially compliant," and Defendants lacked any reasonable basis to state a belief that Caraco was "substantially compliant," for at least the following reasons:

i. As set forth in ¶60, the FDA Form 483 issued the very next day on June 11, 2008, listed at least 14 significant observations evidencing failures in fundamental operating procedures regarding the manufacture of drugs for human consumption, *inter alia*, a lack of written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess, Failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed (*e.g.*, the failure to fully investigate incidents of contaminated, adulterated or out-of-specification drugs or raw materials), Written production and process control procedures are not documented at the time of performance, cGMP training is not conducted on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP

requirements applicable to them, and Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

ii. As alleged in ¶93(l), CW5 stated that he/she was hired by Caraco to "fix everything." Upon his/her arrival at Caraco in July 2008, CW5 immediately faced ***over 1,000 SOPs*** that needed to be updated, and in some cases, ***the SOPs had not been updated in 12 to 14 years***. CW2 indicated, see ¶91(a), there was an utter lack of proper manufacturing practices and quality assurance at Caraco. For example, CW2 noted that standard operating procedures, or "SOP," were changed every day.

iii. As set forth in ¶91(e), according to CW2, ADE reports were consistently delayed and complaints would come in through customer service from a pharmacy or a customer (problems included e.g., insufficient pills in the bottle, broken pills, or a bad reaction to the drug), however, complaints were written up and sent to Quality Assurance; Quality Assurance would review the problem with the originating department and, after a delay in which Caraco management would protect themselves, Caraco would finally file a report. As set forth in ¶90(d), according to CW1, most of the problems at Caraco were in the tablet compression area. According to CW1, ADE reports were filed with the FDA belatedly, as the two employees who filed the Adverse Drug Experience

reports were occupied by their customer service duties, taking phone calls and emails from customers, pharmacies, and distributors.

iv. As set forth in ¶¶93(a)-(l), CW4 confirmed the rampant manufacturing problems at Caraco. He/she stated that in 2008 alone, there were over 1,000 incidents of problems, for example weight variation, contaminants such as hair found in the product, or tablets that were too thick/thin. Indeed, CW4 stated that he/she had seen more hair contamination problems in a week than he/she had seen in all of his/her combined 40 years in manufacturing. CW5 also confirmed that there were serious, rampant problems with tablet variation. CW5 noted that tablet variation was a serious problem, as Digoxin, for example, was a Class 2 drug that could be lethal at the wrong dosage. CW5 noted that in one set of tests weighing over 900,000 tablets, approximately 2% were found to be of the wrong size – an incredibly high ratio of defective product for pharmaceuticals. Indeed, when CW5 first arrived, Caraco was "like the wild west." CW5 also described Movens's intimate knowledge of the rampant problems at Caraco. CW5 attended meetings to address the manufacturing problems at the Company. According to CW5, Movens and several other persons would also attend these meetings, including CW4 who attended the meetings occasionally. Indeed, CW4 confirmed the existence and his/her attendance at some of these meetings. CW5 recalled a Sun Pharma Vice President of Quality attending at least once. While the meetings were first held once a week, they were subsequently held once or twice per day, Monday through Friday at 10 a.m. or 5 p.m., or both. The

meetings were held in a conference room at the Elijah McCoy facility in Detroit adjacent to Movens's office.

v. Defendant Movens was directly involved with addressing, and keenly aware of, the quality issues at the Company. According to CW10, as set forth in ¶98(b), between 2006 and 2008 there would be two separate meetings that were held. There were quality review board meetings and operations meetings. CW10 stated that Defendant Movens gave instructions to all senior management and managers in general in operations and quality that any issues directed at quality would be directed to him first. As a result, CW10 indicated that in some cases, Daniel Barone, the Director of Quality, would find out about quality issues second as Defendant Movens would find out first.

vi. Caraco had failed to remedy deficiencies identified by the FDA in previous observations.

c. The Company was neither "pro-active" in growing its business "appropriately" nor focused on compliance. Indeed, as confirmed by confidential witnesses, the Defendants were keenly bent on growing Caraco's business ***inappropriately*** as they placed intense pressure to increase production at the expense of product quality and regulatory compliance:

i. According to CW2, as set forth in ¶91(g), the Company was trying to make too many drugs at the same time. Indeed, CW2 stated that the whole company was run "by the seat of the pants."

ii. CW3, set forth in ¶92, also indicated that Caraco had "many infractions." It was a "huge production failure" due to the intense pressure to make more drugs despite the lack of infrastructure to do so. For example, according to CW3, an employee would blend the ingredients, then test the mixture to make sure it was correct; but production would consistently start making tablets ***before*** the tests were complete. If a problem was found later, the machine operators were blamed.

iii. Indeed, CW6 confirmed, as set forth in ¶94(a), that as soon as CW6 started, he/she saw things that were "totally wrong." CW6 was concerned about the quality of the product and noted that the set up in the compression stage of manufacturing was incorrect and resulted in metal shavings getting into the product. He/she tried to rectify the problem with management but the ethic was "more about pushing production than quality." According to CW6, every time there was an issue, management wanted to bypass the issue so that they could get production.

iv. CW4 and CW5 similarly recounted the Defendants entire focus was on growing production at the expense of compliance. As alleged in ¶93(d), CW4 stated that even if a product did not meet the in-house specifications, the manufacturing people would release it anyway. According to CW4, the problem stemmed from the attitude of management to "get the tablets out the door." Machines were not allowed to be shut down even when updating SOPs. CW5

corroborated this account, stating that Kaushik Gandhi ordered continued production without interruption – even during SOP revisions.

v. According to CW10, as set forth in ¶98(b), CW10 indicated that while From 7 A.M. to 8 P.M., CW10 reported directly to Defendant Movens, after 9 P.M., however, CW10 received calls from India. On a regular basis, CW10 would have conversations with Sunil Valia, the Wholetime Director of Sun Pharma, who reported to Defendant Shanghvi, the Chairman of both Caraco and Sun Pharma. Sometimes, CW10 would speak directly with Defendant Shanghvi. During conversations with Valia, CW10 would brief Valia on the status of operations at Caraco and targeted goals for production would be assigned. Over the course of years, production was moved up as they hit certain goals. First from 10 lots per month to 40 lots per month. Then from 40 to 80 lots per month. Once they hit 60 lots per month though they were assigned 100 lots per month. When they got to 100 they were given 150 lots per month. CW10 indicated that they achieved 150 lots per month and were given 180. While they never achieved 180 lots per month and only got to 160, they were assigned 240, but that was at the time CW10 left the Company and they were stuck at 160.

104. On July 25, 2008, Caraco issued a press release entitled, "Caraco Pharmaceutical Laboratories, Ltd. Reports Results for the First Quarter of Fiscal Year 2009." Therein, the Company, in relevant part, stated:

> DETROIT, July 25 /PRNewswire-FirstCall/ -- Caraco Pharmaceutical Laboratories, Ltd. (Amex: CPD) posted net sales for the first quarter of Fiscal 2009, ended June 30, 2008, of $108.3 million, as compared to $35.4 million for the corresponding period of Fiscal 2008. This represents an increase of 206% over

> the first quarter of Fiscal 2008. Pre-tax income grew to $14.6 million for the first quarter of Fiscal 2009 as compared to a pre-tax income of $9.6 million during the corresponding period of Fiscal 2008, while net income increased by 11% to $9.4 million in the first quarter of Fiscal 2009, as compared to $8.5 million in the first quarter of Fiscal 2008.
>
> * * *
>
> [Defendant] Movens said,
>
> "The expansion of our facilities should be completed prior to the end of Fiscal 2009. This manufacturing facility along with our new distribution facility, which we recently leased, should provide the capacity we need to supply our customers effectively. ***Our training and succession planning is being enhanced to support our growth and predict future operational efficiencies. We are working with local universities and technical schools in order to provide the proper talented employees required to perform in a highly regulated business. This should create and solidify the pool of personnel required at all levels of the Company to support our growth and provide careers for the local economy. We anticipate improved productivity as our staff continues to increase their experience in their respective positions***."
>
> "Our internal efforts, combined with Sun Pharma, in developing new products have also picked up momentum and this should permit us to grow at the level of our guidance as provided below. Based on our current distribution and sale and marketing agreements with Sun Pharma and our internal portfolio of products and future approved products, we believe we will achieve 25% growth in sales for Fiscal 2009, compared to Fiscal 2008," added Mr. Movens.
>
> (Emphasis added).

105. The foregoing statements were materially false and/or misleading and made with scienter for the reasons stated above in ¶¶101, 103.

106. On July 25, 2008, Caraco filed its Quarterly Report with the SEC on Form10-Q for the 2009 fiscal first quarter. The Company's 10-Q was signed by Defendant Movens and reaffirmed the Company's financial results previously announced on July 25, 2008. Therein, the Company, in relevant part, stated:

FDA COMPLIANCE

The FDA recently concluded an inspection in June 2008. This was a general cGMP inspection and Pre-Approval Inspection for three products. The Company was issued a notice on Form 483. ***The Company has responded accordingly and we believe we remain substantially compliant***. We continue to focus on improving the amount of support in quality assurance, quality control, and manufacturing areas in order to continually improve our performance in quality. This support is derived from the improvement of systems, training on risk management and cGMP, while adding the appropriate level of personnel to support our growth. Additionally we have invested in more automation for improved quality and increase in output with less human intervention. During Fiscal 2008, and currently in Fiscal 2009, in addition to our own internal audits, we have retained outside companies to audit both the laboratory and manufacturing areas of our Company in order to improve and or maintain our systems of operation. These audits were based on a historical look back and offered improvements based on Caraco's future requirements. The audits also included follow up on recommendations of best practices made by the FDA. We have focused our attention for continual improvement of our Corrective and Preventative Actions and cGMP, while adding the appropriate level of personnel to support our growth during Fiscal 2009. The Company has received approvals for seven ANDAs relating to two products since the inspection that concluded in June 2008.

We remain extremely pro-active in regards to growing our business appropriately. We continue to grow the analytical staff, which is currently at 69 employees, thereby enabling the laboratory to better cope with an increased workload with improved timeliness, higher quality, and increased cGMP compliance. Several members of the lab staff attend supplemental professional training courses and conferences, which increases the laboratory's technical and cGMP proficiency. The lab facility has also undergone major upgrades, including a significant increase in working space to improve analyst efficiency and safety. Additional lab instruments and equipment have been purchased which will enable increased compliance with cGMP requirements, cut future costs by enabling in-house rather than contract analyses, and speed sample testing. ***Significant resources have also been spent to improve overall lab operations. Such expenditures demonstrate to the regulators, clients and shareholders that upper management is continually committed to adding quality individuals to the work force, providing the resources necessary to upgrade lab equipment and improve the effectiveness of lab operations and cGMP compliance. Our manufacturing personnel are going through more rigorous training at the time of hire, and thereafter, in order to maintain our compliance and quality.***

(Emphasis added).

107. The foregoing statements were materially false and/or misleading and made with scienter for the reasons stated above in ¶¶101, 103.

108. Defendant Shanghvi – Chairman of Caraco's Board as well as the founder and Managing Director of Sun Pharma, stated in a September 29, 2008 article from the *Business Standard* entitled, "Sun Pharma expects 25% growth in US," that Sun Pharma was poised to profit from Caraco's U.S. operations. Merely ***weeks*** before the FDA issued its Warning Letter to Caraco, Defendant Shanghvi touted Caraco's business and regulatory compliance, as set forth in the *Business Standard* article:

> Even as declining profits from generic medicine sales in the United States are prompting domestic pharma companies to shed their US-centric business, Sun Pharmaceuticals, India's most valuable drug company by market capitalisation, continues its focus on the country with new vigour.
>
> Sun generates 41 per cent of its annual revenues from the US market, a record of sorts among Indian drug firms. The company is bullish on its US prospects and expects 25 per cent growth in the country this year, higher than the 18-20 per cent growth projection it has given for other markets including India.
>
> The United States is the world's largest market for medicines and accounts for nearly 50 per cent of the $780 billion global medicine sales.
>
> In a telephonic interview, Dilip Shanghvi, chairman and managing director of Sun Pharmaceuticals, said the US still offers the best growth platform for the company.
>
> "The US is a large market, where a meaningful generic player can generate several billion dollars as revenues. We are far away from that. Rather than diffusing our energy in other markets, we want to concentrate on this market," Shanghvi said.
>
> The growth projections are not based on any sudden revenue flows arising out of exclusive marketing rights, but on normal sales projections, he added.
>
> Sun is betting high on a region that was found to be tricky by several pharma majors in the past. India's largest drug maker Ranbaxy, which derived 36 per cent

of its global sales from the US in 2004 has brought down its US dependence by spreading across geographies over the last four years.

Ranbaxy's US business was 29 per cent of its global sales in 2005. It came down to 24 per cent last year. Dr Reddy's says that its international sales was primarily driven by Russia, CIS countries, Romania, Vietnam and Venezuela, while its US sales dropped in 2007-08.

The commonly-cited reason for the decline in revenues from drug business in the US is the continuing price erosion.

Contrary to the general trend, Sun's US presence, which was a meagre 2 per cent of its turnover in 1999-2000, grew to 22 per cent in 2005-06 and 23 per cent in 2006-07. It reached 41 per cent of its global turnover in 2007-08.

Unlike several others who source their entire medicine supplies to the US from the low-cost production bases in India, Sun puts in lot of focus on developing its own manufacturing capabilities there.

"Our US operations are routed through Sun's wholly-owned subsidiary Sun Pharmaceutical Industries and Caraco Pharmaceutical Laboratories. Last year (in 2007-08), 30 per cent of our total US sales were made there itself. This should be slightly higher this year," Shanghvi said. According to the company, ***manufacturing flexibility is a key advantage that Sun has built into its US business***. Among three of its manufacturing units in the US, it can handle all kinds of dosage, from varieties of medicines such as tablets, capsules, injections and sprays. A $17-million capacity expansion programme is currently on at its Caraco facility.

Sun remains unperturbed by the intensified regulatory interventions against companies like Ranbaxy on technical issues. "We feel the USFDA will not be a problem if we are operationally focused and disciplined to have all systems in place. We are consistently focused on quality and greater scrutiny will only strengthen our vigil," Shanghvi said.

Sun feels that the increasing competition and declining prices can only help the company improve its cost efficiency. "Tighter cost controls and speedy introduction of generic molecules will ensure profitable cash flow," he said.

(Emphasis added).

109. The foregoing statements were materially false and/or misleading and made with scienter for the reasons stated above in ¶¶101, 103. Indeed, contrary to Shanghvi's representation, Caraco and Sun Pharma were anything but "consistently focused on quality."

110. On October 23, 2008, Caraco issued a press release entitled, "Caraco Pharmaceutical Laboratories, Ltd. Reports Results for the Second Quarter and First Six Months of Fiscal 2009." Therein, the Company, in relevant part, stated:

> DETROIT, Oct. 23 /PRNewswire-FirstCall/ -- Caraco Pharmaceutical Laboratories, Ltd. (Amex: CPD) posted net sales for the second quarter and first six months of Fiscal 2009 of $122.2 million and $230.5 million, respectively, as compared to $41.4 million and $76.8 million, respectively, for the corresponding periods of Fiscal 2008. This represents increases of 195% and 200% over the respective periods of Fiscal 2008. Pre-tax income grew to $12.3 million for the second quarter and $26.9 million for the first six months of Fiscal 2009 as compared to pre-tax income of $4.9 million and $14.5 million, respectively, during the corresponding periods of Fiscal 2008, while net income increased by 82% to $8.4 million in the second quarter of Fiscal 2009, as compared to $4.6 million in the second quarter of Fiscal 2008 and increased to $17.9 million for the first six months of Fiscal 2009, compared to $13.1 million for the corresponding period of Fiscal 2008, an increase of 36%.
>
> * * *
>
> "The expansion of our facilities should be completed prior to the end of Fiscal 2009. The manufacturing facility that we are building, along with our new distribution facility which we recently leased, should provide the capacity we need to supply our customers effectively. ***Our training and succession planning is being enhanced to support our growth and predict future operational efficiencies and improved outcome in quality. We continue to work in collaboration with the State of Michigan and the City of Detroit in conjunction with local universities and technical schools in order to provide the proper talented employees. This should allow us to perform well in what is a highly regulated business. This should also create and solidify the pool of personnel required at all levels of the Company to support our growth and provide careers for the local economy. We anticipate improved productivity as our staff continues to increase their experience in their respective positions."***
>
> "Our internal efforts, combined with Sun Pharma, in developing new products continue to pick up momentum and should permit us to grow at the level of our

> guidance. The current level of growth is at a high level which may not be sustainable. Based on our current distribution and sale and marketing agreements with Sun Pharma and our internal portfolio of products and future approved products, we believe we will achieve 25% growth in sales for Fiscal 2009, compared to Fiscal 2008," added Mr. Movens.
>
> * * *
>
> "We are pleased with our overall results and the direction of the company. We look towards building on our manufacturing sales where possible while measuring the balance required to optimize our gross profit on both distributed and manufactured products. We have many projects in place that should result in improved efficiencies and productivity both from a systems and operational perspective. We will continue to work at lowering costs while maintaining quality throughput in production . . . .,"

(Emphasis added).

111. The foregoing statements were materially false and/or misleading and made with scienter for the reasons stated above in ¶¶101, 103.

112. On October 24, 2008, Caraco filed its Quarterly Report with the SEC on Form10-Q for the 2009 fiscal second quarter. The Company's 10-Q was signed by Defendant Movens and reaffirmed the Company's financial results previously announced on October 23, 2008. Therein, the Company, in relevant part, stated:

> **FDA COMPLIANCE**
>
> The FDA concluded an inspection in June 2008. This was a general cGMP inspection and Pre-Approval Inspection for three products. The Company was issued a notice on Form 483. ***The Company has responded accordingly and we believe we remain substantially compliant.*** We continue to focus on improving the amount of support in quality assurance, quality control, and manufacturing areas in order to continually improve our performance in quality. This support is derived from the improvement of systems, training on risk management and cGMP, while adding the appropriate level of personnel to support our growth. Additionally we have invested in more automation for improved quality and increase in output with less human intervention. During Fiscal 2008, and currently in Fiscal 2009, in addition to our own internal audits, we have retained outside companies to audit both the laboratory and manufacturing areas of our Company.

> We also have and continue to provide external training to our employees as a supplement to our internal training in order to improve and or maintain our systems of operation. All audits are based on a historical look back and offer improvements based on Caraco's future requirements. The audits also included follow up on recommendations of best practices made by the FDA. We have focused our attention for continual improvement of our Corrective and Preventative Actions and cGMP, while adding the appropriate level of personnel to support our growth during Fiscal 2009. The Company has received approvals for seven ANDAs relating to two products since the inspection that concluded in June 2008.
>
> ***We remain extremely pro-active in regards to growing our business appropriately. We continue to grow the analytical staff, which is currently at 69 employees, thereby enabling the laboratory to better cope with an increased workload with improved timeliness, higher quality, and increased cGMP compliance.*** Several members of the lab staff attend supplemental professional training courses and conferences, which increases the laboratory's technical and cGMP proficiency. The lab facility has also undergone major upgrades, including a significant increase in working space to improve analyst efficiency and safety. Additional lab instruments and equipment have been purchased which will enable increased compliance with cGMP requirements, cut future costs by enabling in-house rather than contract analyses, and speed sample testing. ***Significant resources have also been spent to improve overall lab operations. Such expenditures demonstrate to the regulators, clients and shareholders that upper management is continually committed to adding quality individuals to the work force, providing the resources necessary to upgrade lab equipment and improve the effectiveness of lab operations and cGMP compliance. Our manufacturing personnel are going through more rigorous training at the time of hire, and continually thereafter, in order to maintain our compliance and quality.***
>
> (Emphasis added).

113. The foregoing statements were materially false and/or misleading and made with scienter for the reasons stated above in ¶¶101, 103. Additionally, the statements were materially false and/or misleading when made as Defendants knew or were deliberately reckless in not knowing that Caraco was not "substantially compliant." Indeed, in September of 2008 upon CW1's arrival at the Company, many of the procedures were not up to date and were inconsistent with current Good Manufacturing Practices, as stated above in ¶90(a).

IX. THE TRUTH BEGINS TO EMERGE

114. On November 3, 2008, Caraco issued a press release entitled, "Caraco Pharmaceutical Laboratories, Ltd. Receives FDA Warning Letter." Therein, the Company, in relevant part, stated:

> DETROIT, Nov. 3 /PRNewswire-FirstCall/ -- On October 31, 2008, Caraco Pharmaceutical Laboratories, Ltd. (NYSE Alternext US: CPD) received a warning letter from the FDA. The letter was issued as a follow up to the last FDA inspection of the Company's manufacturing facility in Detroit, Michigan which was initiated in May 2008. As previously disclosed, a Form 483 notice was issued in June 2008 following this inspection. ***The Company had responded to all the observations made in the Form 483 within thirty days thereof, and corrective actions were taken and substantially completed***. Subsequent letters noting additional improvements were also provided to the FDA similar to what the Company has done in previous correspondence with the FDA. The observations set forth in the warning letter include, among other things, the inadequate and untimely investigation by the quality control unit of certain incidents at the facility contrary to the Company's standard operating procedures. The FDA considered some of its observations to be repeat observations. The Company believes that the full warning letter, listing all of the observations, will be posted by the FDA shortly on its website at www.fda.gov .
>
> Until the Company's responses to the observations have been clarified and explanations provided to the satisfaction of the FDA, the FDA may in the near term withhold approval of pending new drug applications listing the facility as the manufacturer.
>
> Caraco intends to respond promptly and timely to the FDA within fifteen business days. ***The Company is committed to working cooperatively and expeditiously with the FDA to resolve the matters indicated in its letter.*** Caraco is confident that any remaining concerns will be addressed and resolved.
>
> (Emphasis added.)

115. As a result of the November 3, 2008, press release referenced in ¶114, above, the relevant truth began to be partially revealed. The Warning Letter, itself a partial materialization of the undisclosed risks inherent in pushing rapid drug production at the expense of quality and regulatory compliance, and Defendants' statements partially revealed:

a. That at the time its prior statements were made, Caraco had not been substantially cGMP compliant;

b. That the Company had not significantly altered its manufacturing practices in response to the FDA's observations in the June 2008 Form 483;

c. That the Company had not remedied previous observations from the FDA;

d. And that as a result, the Company could face regulatory sanctions.

116. On this news, over the next three days, shares of Caraco declined by $2.26 per share, or 22.22%, to close on November 5, 2008, at $7.91 per share, on unusually heavy volume.

117. However, the full truth regarding the actual condition of the Company's operations was not revealed. As stated by the confidential witnesses, and as confirmed by the subsequent seizure of ***all*** of the Company's manufactured drugs, the Caraco was plagued by rampant, systemic manufacturing, QA and QC failures that were not being addressed properly. The Warning Letter did not fully apprise the public of the full extent to which Caraco was egregiously noncompliant with cGMP, as confirmed by the confidential witnesses. Furthermore, the Company's foregoing statement that the prior Form 483 had been properly addressed and that the Company remained committed "to working cooperatively and expeditiously with the FDA to resolve the matters" continued to conceal that Defendants, rather than focusing on regulatory compliance, were pushing and would continue to push for increased drug production at the expense of drug quality and regulatory compliance. Indeed, an analyst report issued on December 19, 2008, by IIFL Company, opined that "We believe that the FDA issues at Caraco's Detroit facility would be sorted out soon, and would not be a major dampener on growth rates."

118. On November 24, 2008, Caraco issued a press release entitled, "Caraco Pharmaceutical Laboratories, Ltd. Responds to FDA Warning Letter." Therein, the Company, in relevant part, stated:

> DETROIT, Nov. 24 /PRNewswire-FirstCall/ -- Caraco Pharmaceutical Laboratories, Ltd. (NYSE Alternext US: CPD) announced today that it has timely submitted its response to the FDA warning letter that was received on October 31, 2008. In the warning letter, the FDA requested a response from Caraco within 15 business days, ending November 24, 2008.
>
> As previously disclosed, the warning letter was issued as a follow up to the last FDA inspection of the Company's manufacturing facility in Detroit, Michigan which was initiated in May 2008. Until the Company's responses to the observations have been clarified and explanations provided to the satisfaction of the FDA, the FDA may in the near term withhold approval of pending new drug applications listing the facility as the manufacturer. The Company's sales of current products continue in the normal course of business.
>
> ***The Company is committed to working cooperatively and expeditiously with the FDA to resolve the matters indicated in its letter.*** The Company has requested a meeting with the FDA as a follow up to its response. ***Caraco believes it has addressed the concerns in the warning letter appropriately.***

(Emphasis added).

119. The foregoing statements in ¶118 were materially false and/or misleading when made because the Defendants knew or were reckless in not knowing that the Company had not addressed, and was not addressing, the concerns contained in the October 31 Warning Letter. As alleged in ¶¶101(a)-(b) and observed by CW1, CW4, CW5, CW7 and CW8 in ¶¶90(b)-(d), 93(a)-(i), 93(l), 95(b), 96(a)-(b) and as confirmed by the subsequent seizure of the Company's manufactured drugs, the Company was plagued by rampant, systemic manufacturing, QA and QC failures that were not being addressed properly. Defendants failed to disclose the full extent to which Caraco was egregiously noncompliant with cGMP, as confirmed by the confidential witnesses. Furthermore, the Company's foregoing statement that the Company remained

committed "to working cooperatively and expeditiously with the FDA to resolve the matters" continued to conceal that Defendants, rather than focusing on regulatory compliance, were pushing and would continue to push for increased drug production at the expense of drug quality and regulatory compliance.

120. On January 29, 2009, Caraco issued a press release entitled, "Caraco Pharmaceutical Laboratories, Ltd. Reports Results for the Third Quarter and First Nine Months of Fiscal 2009." Therein, the Company, in relevant part, stated:

> DETROIT, Jan. 29 /PRNewswire-FirstCall/ -- Caraco Pharmaceutical Laboratories, Ltd. (NYSE Alternext US: CPD) posted net sales for the third quarter ended December 31, 2008 and first nine months of Fiscal 2009 of $55.7 million and $286.2 million, respectively, as compared to $81.9 million and $158.6 million, respectively, for the third quarter and first nine months of Fiscal 2008, reflecting a decrease of 32% in the third quarter of Fiscal 2009 and an increase of 80% in the first nine months of Fiscal 2009, as compared to the corresponding periods of Fiscal 2008. The Company earned a net pre-tax income of $6.5 million and $33.4 million, respectively, during the third quarter and first nine months of Fiscal 2009, as compared to a net pre-tax income of $10.1 million and $24.6 million during the corresponding periods of Fiscal 2008. Caraco earned net income of $5.1 million and $22.9 million, respectively, for the third quarter and first nine months of Fiscal 2009, compared to net income of $10.8 million and $23.9 million, respectively, for the corresponding periods of Fiscal 2008.
>
> * * *
>
> [Defendant]Movens stated,
>
> "The expansion of our facilities should provide us the capacity we need to supply our customers effectively. ***We are currently working on streamlining our procedures by adding improved systems and processes which should provide a quality output. Our training and succession planning is being enhanced both internally and by utilizing third parties, to support our growth and predict future operational efficiencies, and improved outcome in quality. We continue to work with local governments, universities and technical schools in order to provide the proper talented employees required to perform in a highly regulated business. We anticipate improved productivity and quality as our newer staff continues to increase their experience in their respective positions."***

"With our planned expansion during Fiscal 2009, it remains important to have the proper management team in place to support the anticipated improvements and growth. Our production capacity and output needs to be increased in order to maximize sales throughout the remainder of Fiscal 2009 and beyond. Though we may decide to incur debt for target acquisitions or other business propositions, we currently remain free of any debt,"

[Defendant] Movens added.

On October 31, 2008, the Company received a warning letter from the Detroit District of the FDA. In this letter, the Agency reiterated some of the concerns detailed in the previous Form 483 issued as a result of our inspection that concluded in June 2008. These concerns included inadequate and untimely investigations by our quality control unit of certain incidents contrary to the Company's standard operating procedures. The FDA also commented on our corrective action plans. The FDA added that failure to promptly correct the deficiencies may result in legal action without further notice, including, without limitation, seizure and injunction. It also noted that other federal agencies may take this warning letter into account when considering the award of contracts. Additionally, the FDA may withhold approval of requests for export certificates, or approval of pending new drug applications. We promptly responded to the warning letter on November 24, 2008 for the deficiencies noted and provided our corrective actions. The Detroit District acknowledged our response on December 22, 2008. It noted that our corrective actions will be evaluated during the FDA's next scheduled inspection of our Detroit facility. It is unlikely that we will receive any approvals for products out of our Detroit facility until after our next inspection. At this time, no further meetings were deemed necessary by the FDA. We have changed our leadership in both manufacturing and quality control in order to better align these areas with our corporate goals.

"***We believe we are substantially compliant with cGMP. We have corrective actions in place and continue to work to improve our quality system. It is our intention to be a model of compliance at all times. We remain confident in our action plan. We continue to invest in improved systems, equipment, training and personnel in quality and manufacturing to improve our overall performance in quality and production. In the last two years we have added a considerable amount of infrastructure in our quality control laboratories. Our current focus is on manufacturing and quality assurance. The Company's sales of current products continue in the normal course of business. We continue to add products to our portfolio through Sun Pharma and its affiliates that we will launch into the US***,"

(Emphasis added).

121. The foregoing statements were materially false and/or misleading and made with scienter for the reasons stated above in ¶113. Additionally, the statements were materially false and/or misleading when made as Defendants knew or were deliberately reckless in not knowing:

a. In addition to the reasons alleged above in ¶101(b), Caraco was not "substantially compliant," and Defendants lacked any reasonable basis to state a belief that Caraco was "substantially compliant," for at least the following additional reasons:

i. As indicated above in ¶75, from December 11, 2008 through December 22, 2008, and the FDA issued observations on Form 483 that included, the inspection of the packaging facilities immediately before use is not done to assure that all drug products have been removed from previous operations, the responsibilities and procedures applicable to the quality control unit are not fully followed, batch production and control records did not include information relating to the production and control of each batch, the persons performing and double-checking the cleaning and maintenance are not dating and signing or initializing the equipment cleaning and use log, and written records of major equipment cleaning, maintenance, and use are not included in individual equipment logs. As alleged in ¶91, CW2 was indirectly involved with the December 2008 FDA audits. The FDA's largest problem was that Caraco had not fixed the problems that it had said it would fix. That is, Caraco had failed to address properly the issues that the FDA had identified in the Form 483 as thought management had "kind of blew it off."

ii. Additionally, as set forth in ¶93(h)-(k), CW5 stated that in or around December 2008, Sun Pharma installed two senior managers at Caraco: Sandeep Mehta as Director of Manufacturing and Sunil Ajmera as Vice President of Manufacturing, and that Mehta and Ajmera both pushed for production "over anything else." According to CW5, while both Mehta and Ajmera ostensibly reported directly to Movens, as also corroborated by CW8's account, it appeared that Mehta and Ajmera, as agents of Sun Pharma, were running Caraco. CW5 stated that when he/she and CW4 approached Movens because it was impossible to meet Mehta's and Ajmera's demands for continued production while developing new SOPs every day, Movens simply replied that "his hands were tied" because he reported to Sun Pharma. Mehta's and Ajmera's control over Caraco's operations and push for production at the expense of regulatory compliance was undeniable. CW5 stated an example in March 2009, where he/she shut down one of the machines and rejected the machine's product. He/she was then called over and told directly by Mehta and Ajmera to not reject anything. Ajmera then directed the Quality Assurance director to put the machine back into operation and to accept the machine's product. The FDA subsequently questioned these actions. CW5 described another incident demonstrating Mehta's and Ajmera's control over Caraco's operations and continued push for production at the expense of regulatory compliance. CW5 rejected a certain drug product due to weight problems. Ajmera indicated that the Company would open up the drug capsules, reclaim the ingredients, and re-make the drug capsules, despite the fact

that the SOPs forbade the reclamation of drug product in this manner. As set forth in ¶96(c), CW8 corroborated that especially after Sun Pharma installed Sunil Ajmera and Sandeep Mehta at Caraco, Movens did not seem to always be in control over Caraco's operations. Also corroborating CW4, CW5, and CW8's testimonies, as set forth in ¶94(d), CW6 stated that he met resistance from Sunil Ajmera and Sandeep Mehta when protesting that the wrong adapters were being used with the scales. As set forth in ¶¶95(b)-(d), CW7 stated that the problems at Caraco were rampant: raw materials, blending, compressing, dispensing, the use of Sejong machines designed for vitamins and not pharmaceuticals. CW7 wanted new machines but was told by Mehta and/or Ajmera that that wasn't going to happen. CW7 corroborated CW4, CW5, CW6 and CW8's statements that Sunil Ajmera and Sandeep Mehta – the two senior managers installed at Caraco by Sun Pharma – exercised broad control over Caraco's operations. Indeed, CW7 viewed Ajmera and Mehta's installation at Caraco as "a reorganization" by Sun Pharma. According to CW7, "Sunil and Sandeep were running the show."

iii. According to the FDA Form 483 from May 2009, on January 13, 2009, 1.352 Kg of Digoxin could not be located. According to CW4, as set forth in ¶93(e), during one FDA inspection, the FDA discovered that Caraco could not account for approximately 1.3 kilograms of Digoxin – a Class 2 drug that could be lethal at the wrong dosage. According to CW4, the FDA was concerned that the Company did not do a thorough investigation because the missing Digoxin

could have been mixed in with other drugs and dangerously released into the market. Instead of conducting a thorough investigation and checking other products, initially the Company only looked at surveillance videos and searched the warehouse before arriving at the assumption that the missing Digoxin had been accidentally thrown out.

iv. As alleged ¶95(c), around January or February 2009, CW7 had a quality issue with foreign matter being found during blending. He/she followed the SOP and called Quality Assurance who told him/her to just continue production and do nothing even though the operator had found 2 bits of paint and a small piece of fiber in the middle of the blending process. No incident report was filed as a result, an example of an occurrence that happened 10's of times. Even though there were lots of issues, according to CW7, most of them were not documented.

b. The Company's sales of current products were not continuing in the normal course of business and Caraco was not continuing to add products to its portfolio through Sun Pharma and its affiliates that would be launched into the US, as evidenced by the Company and Defendant Movens in the June 19, 2009, letter to the FDA that admitted, "With deliberate efforts, since December 15, 2008, we have slowed down new product development and technology transfer activities for continuous focus on cross-functional training and resolution of process and product related discrepancies. Our R&D team is actively participating in conducting in process reviews, investigations, providing additional support in process validations, technical training, conducting audits,

revising batch records, and other areas of expertise to assure proper functioning of compliance and technical systems." Furthermore, the Defendants' insistence on continuing to push production at the expense of regulatory compliance created an acute risk that the Company could face regulatory sanctions which would affect product sales (which eventually did come to happen).

122. On February 3, 2009, Caraco filed its Quarterly Report with the SEC on Form10-Q for the 2009 fiscal third quarter. The Company's 10-Q was signed by Defendants Movens and reaffirmed the Company's financial results previously announced on January 29, 2009. Therein, the Company, in relevant part, stated:

> The FDA concluded an inspection in June 2008. This was a general cGMP inspection and Pre-Approval Inspection for three products. The Company was issued a notice on Form 483. ***The Company responded accordingly.*** On October 31, 2008, the Company received a warning letter from the Detroit District of the FDA. In this letter, the Agency reiterated some of the concerns detailed in the previous Form 483 issued as a result of our inspection that concluded in June 2008. These concerns included inadequate and untimely investigations by our quality control unit of certain incidents contrary to the Company's standard operating procedures. The FDA also commented on our corrective action plans. The FDA added that failure to promptly correct the deficiencies may result in legal action without further notice, including, without limitation, seizure and injunction. It also noted that other federal agencies may take this warning letter into account when considering the award of contracts. Additionally, the FDA may withhold approval of requests for export certificates, or approval of pending new drug applications. We promptly responded to the warning letter on November 24, 2008 for the deficiencies noted and provided our corrective actions. The Detroit District acknowledged our response on December 22, 2008. It noted that our corrective actions will be evaluated during the FDA's next scheduled inspection of our Detroit facility. It is unlikely that we will receive any approvals for product out of our Detroit facility until after our next inspection. At this time, no further meetings were deemed necessary by the FDA. ***We have changed our leadership in both manufacturing and quality control in order to better align these areas with our corporate goals and taken other steps, as stated below, to improve cGMP compliance.***

An inspection of our packaging facility located in Farmington Hills, Michigan was initiated on December 15 2008 as part of a Pre-Approval Inspection. At the conclusion of that inspection on December 22, 2008, the Company was issued a notice on Form 483.Subsequent to the end of the third quarter of Fiscal 2009, the Company filed a response to the FDA Form 483 for the inspection of its packaging facility. ***The Company believes it has responded appropriately to the FDA's concerns, and corrective measures have been put into place. We continue to focus on improving the amount of support in quality assurance, quality control, and manufacturing areas in order to continually improve the performance of our quality system. This support is derived from the improvement of systems, training on risk management and cGMP, while adding the appropriate level of personnel to support our growth. Additionally we have invested in more automation for improved quality and increase in output with less human intervention.*** During Fiscal 2008, and currently in Fiscal 2009, in addition to our own internal audits, we have retained outside companies to audit both the laboratory and manufacturing areas of our Company. The auditors are focusing in detail on compliance concerns noted in our most recent correspondence with the FDA. We also have, and will continue to, provide external training to our employees as a supplement to our internal training in order to improve and or maintain our systems of operation. All audits are based on a historical look back and offer improvements based on Caraco's future requirements. The audits also included follow up on recommendations of best practices made by the FDA. As noted in our response to the FDA, we have hired a new Director of Quality to manage our quality system at all of our facilities. We also continue to gain effective support from Sun Pharma, in both quality systems and personnel, in the areas of quality and manufacturing. ***Further we have changed the leadership in our production area in order to better align this area with our corporate goals. We have focused our attention for continual improvement of our Corrective and Preventative Actions and cGMP, while adding the appropriate level of personnel to support our growth during Fiscal 2009 and we believe we are substantially cGMP compliant. The Company continues to look back historically for any issues or concerns to ensure we remain compliant.***

We remain extremely pro-active in regards to growing our business appropriately. We continue to maintain the analytical staff, which is currently at 69 employees, thereby enabling the laboratory to better cope with an increased workload with improved timeliness, higher quality, and increased cGMP compliance. Several members of the lab staff attend supplemental professional training courses and conferences, which increases the laboratory's technical and cGMP proficiency. The lab facility has also undergone major upgrades, including a significant increase in working space to improve analyst efficiency and safety. Additional lab instruments and equipment have been purchased which will enable increased compliance with cGMP requirements, cut

future costs by enabling in-house rather than contract analyses, and speed sample testing. ***Significant resources have also been spent to improve overall lab operations. Such expenditures demonstrate to the regulators, clients and shareholders that upper management is continually committed to adding quality individuals to the work force, providing the resources necessary to upgrade lab equipment and improve the effectiveness of lab operations and cGMP compliance. Our manufacturing personnel are going through more rigorous training at the time of hire, and continually thereafter, in order to maintain our compliance and quality.***

* * *

Future Outlook

We continue to remain competitive as we continue to grow. We believe that we can manage our costs to continue to be competitive in the future. We have several products in the pipeline awaiting approval by the FDA which should drive future revenue. The Company continues to add products to our portfolio through Sun Pharma and its affiliates that we will launch into the U.S. Due to our size and management structure, we believe that we are able to move swiftly and effectively. ***We are disciplined and have the aptitude to execute our plan. We believe we are substantially compliant with cGMP.*** We have corrective actions in place and continue to work to improve our quality system. It is our intention to be a model of compliance at all times. We remain confident in our action plan. We continue to invest in improved systems, equipment, training and personnel in quality and manufacturing to improve our overall performance in quality and production. In the last two years we have added a considerable amount of infrastructure in our quality control laboratories. ***Our current focus is on manufacturing and quality assurance. With our planned expansion during Fiscal 2009, it remains important to have the proper management team in place to support the anticipated improvements and growth.*** We need to continue to improve our output on research and development by filing more ANDAs with the FDA so as to increase our own manufactured products portfolio. It is our intention to do so both internally and by utilizing third party developers. Our production capacity and output needs to be increased in order to maximize sales throughout the remainder of Fiscal 2009 and beyond. Though we may decide to incur debt for target acquisitions or other business propositions, we currently remain free of any debt.

The expansion of our facilities should provide us the capacity we need to supply our customers effectively. ***We are currently working on streamlining our procedures by adding improved systems and processes which should provide a quality output. Our training and succession planning is being enhanced both internally and by utilizing third parties, to support our growth and predict future operational efficiencies, and improved outcome in quality.*** We continue

> to work with local governments, universities and technical schools in order to provide the proper talented employees required to perform in a highly regulated business. We anticipate improved productivity and quality as our newer staff continues to increase their experience in their respective positions.

(Emphasis added).

123. The foregoing statements were materially false and/or misleading and made with scienter for the reasons stated above in ¶121. Indeed the confidential witness statements regarding, for example, Sun Pharma's installation of Ajmera and Mehta at Caraco in or around December 2008 – who even more aggressively pushed production and sacrificed quality and compliance – was directly contrary to the foregoing statements that "we have changed the leadership in our production area in order to better align this area with our corporate goals," that "[w]e are disciplined…," that "[o]ur current focus is on manufacturing and quality assurance," and that "[w]e continue to focus on improving the amount of support in quality assurance, quality control and manufacturing areas in order to continually improve the performance of our quality system."

124. On March 31, 2009, the previously undisclosed risks associated with pushing production at the expense of drug quality and regulatory compliance (including the use of improper tablet compression machines) partially materialized as Caraco announced a recall of Digoxin tablets due to Caraco's pervasive problems with manufacturing tablets of consistent size and weight. On that day, Caraco issued a press release entitled, "Caraco Pharmaceutical Laboratories, Ltd. Announces a Nationwide Voluntary Recall of All Lots of Digoxin Tablets Due to Size Variability." Therein, the Company, in relevant part, stated:

> DETROIT, March 31 /PRNewswire-FirstCall/ -- Caraco Pharmaceutical Laboratories, Ltd. (NYSE Amex: CPD), a generic pharmaceutical company, announced today that all tablets of Caraco brand Digoxin, USP, 0.125 mg, and

> Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009, which are not expired and are within the expiration date of September, 2011, are being voluntarily recalled to the consumer level. The tablets are being recalled because they may differ in size and therefore could have more or less of the active ingredient, digoxin. The recalled tablets were manufactured by Caraco Pharmaceutical Laboratories, Ltd. This recall is being conducted with the knowledge of the Food and Drug Administration.
>
> Digoxin is a drug product used to treat heart failure and abnormal heart rhythms. It has a narrow therapeutic index and the existence of higher than labeled dose may pose a risk of digoxin toxicity in patients with renal failure. Digoxin toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability, and bradycardia. Death can also result from excessive digoxin intake. A lower than labeled dose may pose a risk of lack of efficacy potentially resulting in cardiac instability. Consequently, as a precautionary measure, Caraco is recalling these tablets to the consumer level to minimize any potential risk to patients.

125. On this news, shares of Caraco declined $1.03 per share, or 22.64%, to close on March 31, 2009, at $3.52 per share, on unusually heavy volume.

126. However, the full truth regarding the actual condition of the Company's operations was not revealed. As stated by the confidential witnesses, and as confirmed by the subsequent seizure of ***all*** of the Company's manufactured drugs, the Caraco was plagued by rampant, systemic manufacturing, QA and QC failures that were not being addressed properly. The recall did not fully apprise the public of the full extent to which Caraco was egregiously not compliant (and not addressing the FDA's concerns in the warning letter) and the fact that Caraco's problems with manufacturing were company-wide, not limited to a single drug. Indeed, the confidential witnesses, along with certain FDA observations, pointed to pervasive manufacturing problems across the board, including tablet size variation, chipped tablets, and pill contamination by foreign objects (metal shavings and hair, for example), caused by both machine- and human-caused failures. Furthermore, the fact that Defendants were continuing to

aggressively push production at the expense of drug quality and regulatory compliance was still concealed from the public.

127. On April 21, 2009, Caraco filed a Current Report with the SEC on Form 8-K. Therein, the Company, in relevant part, stated:

> On April 17, 2009, as a precautionary measure, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") voluntarily initiated a recall of certain product lots manufactured in its Detroit, MI facility. This recall is primarily to the wholesale level. Caraco believes that the sales revenue of the affected lots is approximately $3 million. The recall is being conducted with the knowledge of the Food and Drug Administration.
>
> This recall does not impact other products currently produced and distributed by Caraco. Caraco remains committed to continually improving product quality and manufacturing operations at its Detroit facility.

128. Although the preceding statement referenced in ¶127, above, partially revealed the truth, the statements continued to be materially false and/or misleading when made for the reasons set forth in ¶121, Additionally, the statements were materially false and/or misleading because:

a. As indicated in ¶¶84-85, the FDA documents regarding the recall indicate that the recalls were "FDA Initiated" not "voluntary";

b. The FDA had talked the Company into conducting the recalls.

i. According to the FDA Form 483 from May 2009, on January 13, 2009, 1.352 Kg of Digoxin could not be located. As set forth in ¶93(e), during one FDA inspection, the FDA discovered that Caraco could not account for approximately 1.3 kilograms of Digoxin – a Class 2 drug that could be lethal at the wrong dosage. According to CW4, the FDA was concerned that the Company did not do a thorough investigation because the missing Digoxin could have been

mixed in with other drugs and dangerously released into the market. Instead of conducting a thorough investigation and checking other products, initially the Company only looked at surveillance videos and searched the warehouse before arriving at the assumption that the missing Digoxin had been accidentally thrown out. On April 17, 2009, the Company recalled an additional 410,033 bottles of tablets covering 29 products. According to the FDA recall documents, the "Public Reason for Recall" was "Lack of assurance products do not contain an additional drug ingredient." The recall information further identifies the "Complete Reason for Recall" as "During an FDA inspection, it was determined that the firm was unable to account for all of its digoxin raw material, and the firm elected to recall all products manufactured since the raw material went missing. The firm reports they analyzed retain samples of all lots for digoxin and all results were negative." Moreover, it identifies the recall as being "FDA initiated."

ii. The cause of the other recalled products was related to the Company's reoccurring problems with pills that were either over or undersized. According to the FDA recall documents had been manufactured from "9/30/2008 to 10/16/2008." Further, according to the documents, the "Public Reason for the Recall" as "some of the tablets are oversized or undersized, which will result in the patient not receiving the expected dose." The documents further indicate that the recall was "FDA Initiated" and provides that the "Complete Reason for Recall" as [Caraco] submitted an NDA field alert dated 4/17/09 stating that the tablet weight tolerances are [redacted] mg, but that some tablets in this lot may

> weight as little as [redacted]mg and some may weigh as much as [redacted]mg. The problem was not seen during production, but was discovered during stability testing. After discussion with FDA that this represents a potential health hazard, the firm decided to recall.

129. On May 28, 2009, Caraco issued a press release entitled, "Caraco Pharmaceutical Laboratories, Ltd. Reports Results for the Fiscal Year 2009, Updates on FDA Inspection." Therein, the Company, in relevant part, stated:

> DETROIT, May 28 /PRNewswire-FirstCall/ -- Caraco Pharmaceutical Laboratories, Ltd. (NYSE Amex: CPD) recorded net sales of $337.2 million during Fiscal 2009 compared to $350.4 million during Fiscal 2008. We earned a net pre-tax income of $29.5 million during Fiscal 2009 compared to a net pre-tax income of $42.4 million during Fiscal 2008.
>
> [Defendant] Movens, Caraco's Chief Executive Officer said, "The net sales for fiscal years 2009 and 2008 were $337.2 and $350.4 million, respectively, reflecting a decrease of 4%. The decrease was primarily due to lower sales of our own manufactured products sales, price erosion in both manufactured and distributed product sales and on account of our voluntary product recall initiated during late Fiscal 2009 and the beginning of Fiscal 2010."
>
> We earned a gross profit of $67.8 million in Fiscal 2009, as compared to a gross profit of $84.7 million during Fiscal 2008, reflecting a decrease of 20%. The decrease in gross profit was primarily due to the weight of distributed product sales versus manufactured product sales, price erosion on both distributed and manufactured product sales as well as lower sales of our own manufactured products primarily due from our recent voluntary product recalls. "Although gross profit margins may come down over time due to price erosion, we are confident that our sales growth, expanding product portfolio and successful execution of our business plan will offset any long-term impact,"
>
> [Defendant] Movens said.

* * *

> [Defendant] Movens stated,

"On March 11, 2009 the FDA began an inspection as a follow-up to the October, 2008 Warning Letter. This inspection covers all of the Company's quality and production systems. The inspection concluded on May 12, 2009. The FDA investigators provided the Company with a list of their observations on FDA Form 483. The Company has committed to provide a written response to these observations within 30 days. It is unlikely that we will receive any approvals for any new products out of our Detroit facility until the FDA reviews our remediation response and makes a determination of our status. ***Currently our status remains unchanged. In January 2009 we changed our leadership in both manufacturing and quality control in order to better align these areas with our corporate goals and have taken other steps to improve cGMP compliance and quality system. It should be noted that there were no deficiencies identified during the FDA inspection in the Quality Control Laboratory which supports and tests all of our products before they are released to the market."***

[Defendant] Movens added,

"We continue to attract and hire talented individuals, to improve our operation and we continue to improve both our service levels and expand our customer base where possible. Based on our own development pipeline and the current agreements we have with Sun Pharma along with other third party developers, we believe we will continue to perform well in our industry. Though we remain hopeful, the uncertainty of the time lines associated with new approvals based on our status with the FDA limits our view on our growth in the near term. Since FDA approvals are a significant part of any generic company's growth we have determined that we will not provide any further guidance related to our top line growth. We remain confident that our basic fundamental performance over the course of Fiscal 2010 will provide sufficient disclosure to our shareholders. The recent voluntary recalls previously disclosed have had a negative impact on the Company's performance and may continue to have a negative impact in the near term. Price erosion on both manufactured and distributed products also contributed to the decline of our top line growth. ***We remain confident that our corrective actions in compliance and quality will ultimately let us gain back our momentum of growth that we have enjoyed over the last several years.*** We are fortunate to have a successful marketing platform and Sun Pharmaceutical Industries Inc.'s product line to complement our manufacturing products business."

(Emphasis added.)

130. The statements continued to be materially false and/or misleading when made for the reasons set forth in ¶¶121, 123, 128. In addition to the reasons alleged above in ¶101(b), Caraco was nowhere near cGMP compliant for at least the following additional reasons:

a. As indicated above in ¶80, on May 12, 2009, the Company received another FDA Form 483 following an inspection commenced on March 11, 2009. The FDA's observations on Form 483 included: that records fail to include an individual inventory record of each reconciliation of the use of each component with sufficient information to allow determination of any associated batch or lot of drug product; that written procedures are not followed for the storage and handling of components; the failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed; the failure of written procedures to describe in sufficient detail the receipt, identification, storage, and handling of components; the failure to establish control procedures to monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and the drug product, particularly thick, soft, thin, broken and imperfect appearance tablets; the failure to follow written production and process control procedures in the execution of production and process control functions; the failure to include weights and measures of components used in the course of processing drug product batches; the failure to establish time limits when appropriate for the completion of each production phase to assure the quality of the drug product; the failure to justify deviations from written production and process control procedures; the failure to write and fully follow the responsibilities and procedures applicable to the

quality control unit; the failure to extend investigation of an unexplained discrepancies to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy; the failure to assure that individuals responsible for supervising the processing of a drug product have the training and experience to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess; the failure of written records of investigations of drug complaints to include the findings of the investigation and the follow-up, including investigations relating to numerous size and weight variations in drug tablets over a variety of products; the failure to maintain records so that the data can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures; the lack of enough adequate space for the orderly placement of equipment and materials to prevent mix-ups and contamination between different components and in-process materials; the failure of equipment used in the manufacture, processing, packing or holding of drugs to have appropriate design to facilitate operations for its intended use; and the failure of written procedures for cleaning and maintenance to include parameters relevant to the operation.

b. As alleged in ¶90, CW1 was involved with the May 2009 FDA audit. The FDA personnel who conducted the audit were concerned that Caraco could not account for some missing inventory. They also disapproved of the ERP system. Additionally, the FDA was particularly concerned that the changes that senior management had previous told the FDA would be made had not been properly implemented. Specifically, Caraco

had told the FDA that they would put a bar coding system in place. But, according to CW1, Caraco was trying to develop a system in-house instead of buying an off the shelf product – just as it had with the insufficient ERP system. The system was not fully implemented during CW1's employment, but based on his/her initial experience, the system was very hard to use – only the people who had written the software could understand how to use it. According to CW1, it was important to fully record movements of raw materials as they occurred in the dispensing area. But operators were not trained or allowed to enter these "transactions." As a result, senior people such as himself/herself were required to make the entries, long after they had happened, based on logs that operators were supposed to complete. But even CW1, who holds a Chemistry Degree, found it difficult to understand and use the ERP system.

131. On June 15, 2009, Caraco filed its Annual Report with the SEC on Form10-K for the 2009 fiscal fourth quarter and full year. The Company's 10-K was signed by Defendants Movens and Shanghvi and reaffirmed the Company's financial results previously announced on May 28, 2009. Therein, the Company, in relevant part, stated:

FDA Compliance

During FY 2009, The FDA inspected both the Elijah McCoy manufacturing facility and the Farmington packaging facility. Forms FDA 483 were issued at the conclusion of both inspections detailing the FDA investigators' observations. Responses to these observations were submitted to the FDA detailing the Company's actions taken in response to the observations. On October 31, 2008, the Company received a warning letter from the Detroit District of the FDA. In this letter, the Agency reiterated some of the concerns detailed in the previous Form 483 issued as a result of our inspection that concluded in June 2008. These concerns included inadequate and untimely investigations by our quality control unit of certain incidents contrary to the Company's standard operating procedures. The FDA also commented on our corrective action plans. The FDA added that failure to promptly correct the deficiencies may result in legal action without

further notice, including, without limitation, seizure and injunction. It also noted that other federal agencies may take this warning letter into account when considering the award of contracts. Additionally, the FDA may withhold approval of requests for export certificates, or approval of pending new drug applications. We promptly responded to the warning letter on November 24, 2008 for the deficiencies noted and provided our corrective actions. The Detroit District acknowledged our response on December 22, 2008. It noted that our corrective actions would be evaluated during the FDA's next scheduled inspection of our Detroit facility. On March 11, 2009 the FDA began an inspection as a follow-up to the October, 2008 warning letter. This inspection covered all the quality and production systems of the Company and concluded on May 12, 2009. The FDA investigators provided the Company with a list of their observations on FDA Form 483. Some of the observations were relative to the recent recalls and compliance, whereas others were focused on inventory controls. On March 31, 2009, we recalled all tablets of Digoxin, USP, 0.125 mg, and Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009 to the consumer level. As a precautionary measure, in April 2009, we initiated a recall of certain product lots manufactured in our Detroit, MI facility, primarily to the wholesale level. The total sales revenue, related to these recalls, we believe, is approximately $4.2 million. These recalls were voluntarily initiated by the Company with the knowledge of the FDA. The recalls were made as a precautionary measure. The Company has committed to provide a written response to these observations within approximately 30 days. We have not obtained FDA approvals of our ANDAs since the first quarter of Fiscal 2009. It is unlikely that we will receive any approvals for product out of our Detroit facility until the FDA reviews our remediation response and makes a determination of our status. Currently our status remains unchanged. ***We have changed our leadership in both manufacturing and quality control in order to better align these areas with our corporate goals and taken other steps, as stated below, to improve cGMP compliance.***

Customer confidence could diminish based on the recent recalls and our status with the FDA. As previously disclosed it is possible that certain government contracts could be affected by the Warning Letter and our current status. In the fourth quarter of Fiscal 2009, due to our status with the FDA, the Veterans Administration has not renewed certain product contracts we had with them that were expiring. Once we have resolved our current issues with the FDA, we may regain this business when these contracts come up for renewal, which occurs on an annual basis.

We continue to focus on improving the amount of support in quality assurance, quality control, and manufacturing areas in order to continually improve the performance of our quality system. This support is derived from the improvement of systems, training on risk management and cGMP, while adding

the appropriate level of personnel to support our growth. Additionally we have invested in more automation for improved quality and increase in output with less human intervention. During Fiscal 2008, and currently in Fiscal 2009, in addition to our own internal audits, we have retained outside companies to audit both the laboratory and manufacturing areas of our Company. The auditors are focusing in detail on compliance concerns noted in our most recent correspondence with the FDA. We also have, and will continue to, provide external training to our employees as a supplement to our internal training in order to improve and or maintain our systems of operation. All audits are based on a historical look back and offer improvements based on Caraco's future requirements. The audits also included follow up on recommendations of best practices made by the FDA. ***We continue to gain effective support from Sun Pharma, in both quality systems and personnel, in the areas of quality and manufacturing. Further we have changed the leadership in both our quality and production areas in order to better align these areas with our corporate goals of compliance and quality. The new teams in these areas are affecting change as rapidly as required in order to provide continual improvement. We have focused our attention for continual improvement of our Corrective and Preventative Actions and cGMP, while adding the appropriate level of personnel to support our growth during Fiscal 2009 and we believe we are substantially cGMP compliant. The Company continues to look back historically for any issues or concerns to ensure we remain compliant. Our manufacturing personnel are going through more rigorous training at the time of hire, and continually thereafter, in order to maintain our compliance and quality.***

We remain extremely pro-active in regards to growing our business appropriately. We continue to maintain the analytical staff, which consists of approximately 70 employees, thereby enabling the laboratory to better cope with an increased workload with improved timeliness, higher quality, and increased cGMP compliance. Several members of the lab staff attend supplemental professional training courses and conferences, which increases the laboratory's technical and cGMP proficiency. The lab facility has also undergone major upgrades, including a significant increase in working space to improve analyst efficiency and safety. Additional lab instruments and equipment have been purchased which will enable increased compliance with cGMP requirements, cut future costs by enabling in-house rather than contract analyses, and speed sample testing. Significant resources have also been spent to improve overall lab operations. ***Such expenditures demonstrate to the regulators, clients and shareholders that upper management is continually committed to adding quality individuals to the work force, providing the resources necessary to upgrade lab equipment and improve the effectiveness of lab operations and cGMP compliance.*** Our Quality control lab operations were not cited for any observations during the FDA's last inspection of our facility.

* * *

Future Outlook

Though Fiscal 2009 has seen several challenges in manufacturing and compliance, we believe that the steps that we have taken will provide for a better outcome going forward. ***We have hired experienced people in these areas to correct such areas where we may be deficient.*** Further, we have third party consultants that are providing guidance on remediation for such improvements. ***Sun Pharma has provided assistance and guidance from its own corporate quality group. It also continues to provide improvements for our quality systems. We believe the Company's future performance in these areas will be capable of supporting our efforts in providing a quality product on time to satisfy our customers' needs.*** Though near term sales of manufactured products may face some challenges, we believe we are effecting the changes required to improve our performance on manufactured product sales on a long term basis. We will continue to compete effectively in the market we serve. Due to our size and management structure, we believe that we will execute our plan effectively, on a long term basis. ***We are disciplined and have the aptitude to execute our plan.*** Though we have made considerable improvements in our quality systems, we still have improvements to implement and measure as part of our continual improvement process. With this in mind, we believe we are substantially compliant with cGMP. ***We continue to invest in improved systems, equipment, training and personnel in quality assurance, quality control and manufacturing to improve our overall performance in quality. We have added considerable amount of infrastructure in quality and expect that we will continue to add additional infrastructure in manufacturing.***

The expansion of our facilities should provide the capacity we need to supply our customers effectively. ***Our training and succession planning is being enhanced to support our growth and predict future operational efficiencies. We are working with local universities and technical schools in order to provide the proper talented employees required to perform in a highly regulated business.*** We anticipate improved productivity as our staff continues to increase their experience in their respective positions. Our platform is poised for growth. We have the capacity, infrastructure and capability to perform well in the industry. ***The personnel that we have added have improved the competency level which should improve the performance of our manufacturing and quality areas.*** Our distribution and marketing capability continues to offer its standard of excellence to maximize our market share.

. . . We remain confident that our reporting of our basic fundamental performance over the course of Fiscal 2010 will provide sufficient disclosure to our

> shareholders and others. The recent voluntary recalls previously disclosed, have had a negative impact on the Company's performance and may continue to have a negative impact in the near term. ***We remain confident that our implementation of corrective actions in compliance and quality will ultimately let us gain back our momentum of sales growth that we have enjoyed over the last several years.*** We have a successful marketing platform and also have Sun Pharma's product line to complement our manufacturing products business.

(Emphasis added.)

132. The foregoing statements were materially false and/or misleading and made with scienter for the reasons stated above in ¶130.

X. EVENTS AT THE END OF THE CLASS PERIOD

A. Day of Reckoning: With Caraco Unable to Continue Concealing Its Severe and Systemic Manufacturing Problems and Unable to Address the FDA's Concerns, U.S. Marshals Seize Drug Products Manufactured by Caraco

133. On June 24, 2009, the United States Attorney for the Eastern District of Michigan filed a complaint for forfeiture of adulterated articles of drug (the "Forfeiture Complaint") on behalf of the United States directed at all articles of drug located at Caraco's Elijah McCoy, Farmington Hills or Wixom, Michigan facilities. The Forfeiture Complaint, verified under penalty of perjury by Judith Putz of the FDA, alleged that the FDA had issued a Warning Letter to Caraco on October 31, 2008 identifying numerous significant GMP violations identified during a May 1-June 11, 2008 but that Caraco, despite repeatedly representing it had corrected the deficiencies, was still in continuing and significant violation of cGMP as admitted in its June 19, 2009 letter to the FDA. These violations included, but were not limited to, the following: (1) failure to follow written procedures for the storage and handling of components resulting in, for example, the placement and use of raw materials without proper documentation resulting in the loss of toxic digoxin drug substance; (2) failure to follow written procedures for the execution of

the production and process control functions for "charge-in" of components resulting in, for instance, the use of the wrong components in batch processing of drugs; (3) failure to maintain accurate inventory records of components resulting in, for example, 27 inventory discrepancies that could not be reconciled; (4) failure to have written procedures for production and process control, resulting in, for example, the manufacture of tablet drug products before adequately evaluating processing issues; (5) the failure to establish and follow written procedures describing in-process controls or tests, resulting in, for instance, reliance on visual inspection to remove defective tablets even though the company's own investigations revealed that the visual culling process was not effective; (6) failure to use appropriate equipment, resulting in, for instance, the inability to assure consistent quality for Digoxin drug products; (7) failure to conduct thorough investigations of unexplained discrepancies in drug manufacture causing, for instance, the failure to timely investigate out of specification inventory reconciliation for nine different drugs and the failure to investigate the root cause of the discrepancies; (8) failure to establish and follow written procedures applicable to the quality control unit, resulting in, for instance, changes in material weighing and machinery that lead to subsequent problems in manufacturing; and (9) failure to conduct follow-up to investigations of complaints, resulting in, for example, the failure to evaluate the potential health hazard of thick or thin tablets as it regards under- or supra-potency.

134. On June 25, 2009, the market was shocked by news reports that federal agents had raided the Company's Michigan facilities and seized products manufactured by the Company, including ingredients used by the Company in manufacturing its products. That day, the FDA

issued a press release entitled, "U.S. Marshals Seize Drug Products Manufactured by Caraco Pharmaceutical Laboratories Ltd." Therein, the FDA, in relevant part, stated:

> FDA acts to prevent repeated drug quality problems
> U.S. Marshals, at the request of the Food and Drug Administration, today seized drug products manufactured by Caraco Pharmaceutical Laboratories Ltd. (Caraco), at the company's Michigan facilities in Detroit, Farmington Hills, and Wixom. The seizure also includes ingredients held at these same facilities. "The FDA is committed to taking enforcement action against firms that do not manufacture drugs in accordance with our good manufacturing practice requirements," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "Compliance with these standards prevents harm to the public."
>
> This action follows Caraco's continued failure to meet the FDA's current Good Manufacturing Practice (cGMP) requirements, which assure the quality of manufactured drugs. Through this seizure, the FDA seeks to immediately stop the firm from further distributing drugs until there is assurance that the firm complies with good manufacturing requirements.
>
> Since January 2009, Caraco has initiated voluntary recalls of drug products to protect the public from potentially defective medications. The recalls involved manufacturing defects, including oversized tablets and possible formulation error.
>
> The FDA has determined that the seizure of Caraco's drugs may create a shortage of one product, choline magnesium trisalicylate oral tablets, which are commonly used as pain relievers. The FDA recommends in the event of a shortage, that health care providers consider alternative treatments that are safe and effective. Consumers and health care providers who are unable to obtain any of Caraco's products should contact the FDA Drug Shortage Program by e-mail at drugshortages@fda.hhs.gov, or by telephone at 888-463-6332 or 301-796-3400.
> The FDA's most recent inspection of Caraco, completed in May 2009, found unresolved violations of cGMP requirements. Today's seizure is intended to lead to major changes at Caraco's facilities.
>
> If the FDA identifies further significant problems, which pose risks to patient safety with any Caraco drug products on the market, the agency will take appropriate additional regulatory action and immediately notify the public.
>
> "The FDA will continue to take swift, aggressive enforcement action when firms are identified as being in violation of our manufacturing requirements," said Michael Chappell, FDA acting associate commissioner for regulatory affairs.

> Seizure of drug products is an effective remedy when there is evidence of continued poor compliance with cGMPs. Following a drug product seizure, companies often agree to a wide range of changes and improvements to their drug manufacturing practices at their facilities.

(Emphasis in original.)

135. On June 25, 2009, as a result of the FDA's seizure action, Caraco issued a press release entitled, "Caraco Pharmaceutical Laboratories, Ltd. Announces FDA Action" Therein, the Company, in relevant part, stated:

> DETROIT, June 25 /PRNewswire-FirstCall/ -- Caraco Pharmaceutical Laboratories, Ltd. (NYSE Amex: CPD) announced that U.S. Marshals, at the request of the Food and Drug Administration, today arrived and seized drug products manufactured in its Michigan facilities. The seizure also included ingredients held at these same facilities. The FDA's most recent inspection of Caraco's Detroit facility, completed in May 2009, found unresolved violations of cGMP requirements as previously disclosed in our last SEC filing on Form 10-K filed June 15, 2009. The Company believes that corrective actions have been made and continual improvements are in process. The FDA has only seized products manufactured in its Michigan facilities. Products distributed by Caraco that are manufactured outside of these facilities are not impacted. While we have not fully determined the impact of this action by the FDA on our financial condition, we believe that it may have a material adverse effect on our near term operations. We anticipate working with the FDA to resolve these concerns as effectively and expeditiously as possible. The Company will provide updates as information becomes available.

136. On this news, shares of Caraco declined $1.79 per share, or 42.82%, to close on June 25, 2009, at $2.39 per share, on unusually heavy volume.

137. On June 26, 2009, the Company issued a press release entitled, "Caraco Pharmaceutical Laboratories, Ltd. Updates on Financial Position." Therein, the Company, in relevant part, stated:

> DETROIT, June 26 /PRNewswire-FirstCall/ -- Caraco Pharmaceutical Laboratories, Ltd. (NYSE Amex: CPD), in an effort to update our shareholders, is providing additional information in regards to our financial position in light of the recent FDA action. The products in our inventory related to the FDA action are

currently being identified. The early estimated value of this inventory is in the range of $15 to $20 million.

The products subject to seizure do not impact products on hand manufactured by third parties under their own label or manufactured for Caraco under the Caraco label. It also does not impact products recently sold into the market manufactured by Caraco.

Based on the estimated sales of distributed products and Caraco products manufactured by third parties, we believe that the profit generated from those products will cover our estimated ongoing expenses. Further, our cash balance as of June 25, 2009 is approximately $64 million which includes a loan of $18 million. Accordingly, we expect that our financial position will allow the Company the time to resolve its pending FDA issues.

B. The Aftermath: Post-Class Period Events

138. The FDA seizure crippled Caraco's operations. On July 26, 2009, Caraco announced that it was indefinitely laying off ***350 employees*** "in order to align its expenses with the current voluntary cessation of its manufacturing operations in connection with the recent action by the [FDA]." The 350 employees represented ***over half*** of the Company's approximately 650 workers at the time,

139. Furthermore, Defendant Movens's reign as CEO and director of Caraco soon came to an end. On July 28, 2009, Defendant Movens resigned as CEO and director of Caraco and was replaced by Jitendra N. Doshi. In a press release issued that day, Caraco stated that "[d]uring Mr. Movens' tenure, Caraco experienced substantial product expansion and revenue growth."

140. The fallout continued. On September 20, 2009, one of the independent directors on Caraco's Board, Georges Ugeux, resigned from his position, citing in his resignation letter his "fundamental disagreements with the majority shareholder, Sun [Pharma] and senior

management of Caraco [] over issues of corporate governance and the fiduciary role of independent directors."

141. While Caraco, in a press release issued September 23, 2009, attempted to spin Ugeux's resignation as being based on "disagreements relat[ing] to the role of the independent directors ***going forward*** in managing the FDA actions" (emphasis added), Ugeux quickly dispelled such a notion. In his September 23, 2009 response letter, Ugeux stated clearly that his disagreement was with Sun Pharma's and Caraco management's behaviors ***leading up to, and potentially contributing to, the FDA seizure***:

> I have reviewed the Form 8-K filed by Caraco Pharmaceutical Laboratories, Inc. (the "Company") on September 23, 2009, including the Company's press release filed as an exhibit thereto, disclosing my resignation and feel compelled to respond. The Company's belief as to the nature of my disagreement as being the actions of the Company "going forward in managing the FDA actions" is an ***inaccurate characterization***. Rather, as I have reiterated consistently throughout the past several weeks, ***the basis for my disagreement is management's and the majority shareholder's absolute refusal to permit a focused independent look at corporate governance matters to determine if they contributed to the events leading up to the FDA seizure***. In my view, what might be learned from such an exercise would provide an opportunity to re-evaluate and correct, if appropriate, corporate governance going forward for the benefit of all shareholders of the Company.

(Emphasis added.)

142. In a September 29, 2009 press release, Caraco announced that it had entered into a consent decree with the FDA providing "a series of measures that, when satisfied, will permit Caraco to resume manufacturing and distributing those products that are manufactured in its Detroit area facilities." However, under the terms of the consent decree, "Caraco's cessation of manufacturing operations will continue until it receives written notification from independent experts and the FDA that it is in compliance with the degree and regulations…." As of the date

of this filing, nearly eight months after the FDA seizure of its drugs, Caraco still has not resumed manufacturing activities at its Michigan facilities.

XI. CLASS ACTION ALLEGATIONS

143. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased Caraco's securities between May 29, 2008 and June 25, 2009, inclusive (the "Class Period") and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

144. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Caraco's securities were actively traded on the American Stock Exchange ("AMEX"). While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Millions of Caraco shares were traded publicly during the Class Period on the AMEX and as of June 10, 2009, shortly near the end of the Class Period, the Company had 37,458,194 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by Caraco or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

145. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

146. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

147. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) Whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Caraco; and

(c) To what extent the members of the Class have sustained damages and the proper measure of damages.

148. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XII. UNDISCLOSED ADVERSE FACTS

149. The market for Caraco's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Caraco's securities traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired Caraco's securities relying upon the integrity of the market price of the Company's securities and market information relating to Caraco, and have been damaged thereby.

150. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Caraco's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. Said statements and omissions were materially false and/or misleading in that they failed to disclose material adverse information and/or misrepresented the truth about Caraco's business, operations, and prospects as alleged herein.

151. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Caraco's cGMP compliance, financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company's compliance with good manufacturing practices, its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or

misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

XIII. LOSS CAUSATION/ECONOMIC LOSS

152. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class. The Plaintiffs and the Class purchased Caraco securities at artificially-inflated prices – prices that declined when the truth about Caraco's regulatory compliance failures, which Defendants had hidden from the markets, was revealed. The issues about which Defendants misled the market were the very issues that caused Caraco's securities to decline in value, and thus the very issues that caused the injuries to Plaintiffs and the Class. In short, Defendants concealed from the market the very real risk that Caraco's deliberate and aggressive mandate to push production at the expense of drug quality and regulatory compliance – and the resulting failures to comply with cGMP – would lead to FDA sanctions against the Company.

153. During the Class Period, as alleged herein, the Defendants engaged in a scheme to deceive the market and in a course of conduct that artificially inflated the value of Caraco's securities and operated as a fraud on Class Period purchasers of Caraco securities by misrepresenting and failing to disclose: (1) Caraco's deliberate and aggressive mandate to push production at the expense of drug quality and regulatory compliance and the resulting failures to comply with cGMP; (2) the risk to Caraco posed by its consistent failure to comply with cGMP and other regulations; and (3) the significance of the risks posed by the FDA's oversight actions related to Caraco, in light of Caraco's failure to comply with cGMP and other applicable

regulations. However, as shown herein, subsequently when the truth concerning Caraco's failure to comply with applicable regulations entered the market and became apparent to investors, the price of Caraco's securities materially declined as the artificial inflation dissipated. Since the disclosures that caused such declines related to Caraco's cGMP and related regulatory violations, and since these matters were the subject of Defendants' misrepresentations, Defendants' misrepresentations proximately caused the declines in the securities' values.

154. The price of the Company's securities significantly declined on an unusually high volume of trades when the truth regarding defendants' misrepresentations, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses. The disclosure of the truth took place through a series of partial revelations/disclosures between November 3, 2008 and June 25, 2009 that revealed the seriousness of the FDA observations made during the May-June 2008 cGMP inspection, the effect the failure to comply with cGMP was having on Caraco's production of drug tablets and, ultimately, the complete failure of Caraco's efforts to bring itself into compliance with FDA requirements despite representing it was moving efficiently and immediately to address FDA concerns.

155. For example, on November 3, 2008, Caraco issued a press release revealing that it had received an FDA Warning Letter. This partial disclosure only began to inform the market of the FDA compliance and cGMP issues that would prove so damaging to the company. Despite the fact that the disclosure was so limited, over the next three days, shares of Caraco declined by $2.26 per share, or 22.22%, to close on November 5, 2008, at $7.91 per share, on unusually heavy volume of 412,800 shares trading hands over the course of the three days.

156. Likewise, on March 31, 2009, Caraco issued a press release announcing its recall of Digoxin tablets. Once again, this disclosure was very limited, and did not disclose the full scope of Caraco's compliance problems to the market, including that the problems went way beyond the one product being recalled. Despite the disclosure's limitations, shares of Caraco declined $1.03 per share, or 22.64%, to close on March 31, 2009 at $3.52 per share, on unusually heavy volume of 329,200 shares traded.

157. Then, on June 25, 2009, the market was shocked by news reports that federal agents had raided the Company's Michigan facilities and seized products manufactured by the Company, including ingredients used by the Company in manufacturing its products. This was the sort of drastic action that Defendants had known was possible or even likely, given their serious and pervasive compliance and quality control problems that they had concealed from the market. On this news, shares of Caraco declined $1.79 per share, or 42.82%, to close on June 25, 2009 at $2.39 per share, on extremely heavy volume of 2,041,300 shares.

158. The price declines directly and proximately resulting from the above discussed disclosures and events were not caused by market conditions, industry news, randomness, or by Caraco-related information unrelated to the alleged fraud. Each of the above referenced disclosures partially corrected the false and misleading information previously provided to the market for which the Plaintiffs, on behalf of themselves and the Class, seek to be compensated. These misrepresentations concealed the risks posed by the cGMP violations – risks that were fully realized when the federal government raided Caraco's facilities. It was these concealed risks that caused the securities' price declines, and thus the Defendants' misrepresentations caused the damages suffered by Plaintiffs and the Class members.

XIV. ADDITIONAL SCIENTER ALLEGATIONS

159. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Caraco, his/her control over, and/or receipt and/or modification of Caraco's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Caraco, participated in the fraudulent scheme alleged herein.

160. As a specific example, the FDA's warnings to Caraco prior to and during the class period were extensive, and they were consistent with one another. These warnings, which were provided to the highest ranking managers of Caraco over the course of years, including the individual Defendants, placed the Defendants on notice of the severe, pervasive cGMP violations and related problems that plagued Caraco's facilities – violations and problems that were flatly inconsistent with Caraco's repeated assurances to investors, such as its repeated assurance that it was "substantially compliant" with FDA requirements. These violations were of such a simple, basic, pervasive and serious nature, particularly given the risk to the consuming public of using contaminated and/or over- and under-sized tablets that it creates strong and direct evidence of scienter.

161. Despite these cGMP violations, Caraco insisted to its investors that it was substantially compliant, or otherwise attempted to minimize the significance of the violations. The misrepresentations and omissions regarding compliance with cGMP related to central, day-to-day operational matters for both Caraco and the Individual Defendants and were expressly treated as critical by them. On many occasions, Caraco's warnings from the FDA were nearly contemporaneous with its reassurances to investors. On other occasions, the company would try to assure the FDA that it recognized the seriousness of the violations – at the same time that it was suggesting to investors that the violations were not serious. For example:

a. On July 10, 2008, Caraco responded to the FDA's June 11, 2008 Form 483, telling the FDA that it was undertaking a "comprehensive systemic correction" of its SOP. But just over two weeks later, in its July 25, 2008 10Q, it advised investors that it was "substantially compliant" with the FDA's requirements.

b. On October 24, 2008, Caraco filed its 10Q, which disclosed the FDA inspection from the past May and June, but claimed that "we believe we remain substantially compliant" with FDA requirements. Yet only a week later, on October 31, 2008, the FDA issued Caraco a warning letter, addressed to Movens, stating that this inspection had revealed "significant deviations from [cGMP] regulations," which "cause the drug products being manufactured at your facility to be adulterated within the meaning of … the Federal Food, Drug, and Cosmetic Act (the Act)..."

c. On November 24, 2008, defendant Movens responded on behalf of Caraco to the October 31, 2008 Warning Letter. In his response, Movens stated that "[w]e recognize the seriousness of the violations and we would like to confirm that we have

taken appropriate actions to correct the deficiencies in order to ensure compliance with the regulations."

d. On May 12, 2009, the FDA issued Caraco another Form 483 reiterating its serious concerns about the company's operations. Caraco turned to doublespeak. On May 28, 2009, it released a press release that failed to reveal the full seriousness of the FDA's concerns, and on June 15, 2009, Caraco issued its 10k, in which it represented that "we believe we are substantially cGMP compliant." Yet, just a few days later, the company's June 19, 2009 response to the FDA indicated that Caraco "completely understands the serious nature of the allegations." Thus, Caraco was telling the FDA that it understood the magnitude of its problems and the seriousness of the FDA's concerns – all while minimizing the problems and the FDA's concerns in communications with investors, and while failing to disclose to investors the true risk that these developments posed to Caraco.

e. Caraco's reassurance to its investors in the June 15, 2009 10k that it believed it was "substantially cGMP compliant" was revealed to be untrue when, just days later on June 24, 2009, the United States Attorney for the Eastern District of Michigan filed the Forfeiture Complaint, alleging that Caraco, despite repeatedly representing it had corrected the deficiencies, was still in continuing and significant violation of cGMP.

162. Moreover, the statements to the FDA were themselves misleading. The statements to the FDA constantly assured that the cGMP violations would be fixed. Yet Caraco failed to fix the violations – the FDA kept finding the same violations over and over again.

Eventually, after Caraco had strung the FDA along for too long, the FDA was forced to take decisive action.

163. Additionally, the accounts of the confidential witnesses buttress the FDA's perception of widespread problems. The problems described were so pervasive, and so closely related with the company's primary operations, that management could not have been unaware of the problems. What is more, many of the reports from the confidential witnesses directly concern conversations with defendant Movens or meetings that he attended. These reports make clear that Movens had direct and constant access to information concerning Caraco's manufacturing processes and its failure to comply with CGMP. They also make clear that Caraco never adequately responded to the FDA's observations regarding the failure to comply with cGMP, despite its repeated assurances that it would do so. In fact, defendants gave inconsistent and untrue explanations to the FDA in an effort to justify its conduct.

164. Confidential witness statements demonstrate that the Defendants either knew about Caraco's manufacturing problems and egregious noncompliance with cGMP, or had direct access to information that would indicate as much:

a. CW4 and CW5 both communicated serious manufacturing problems with Movens directly, especially with regards to Caraco's misuse of "Sejong" compression machines (machines intended to produce small quantities of vitamins, not large quantities of pharmaceuticals);

b. CW5's complaint to Movens that it was impossible to meet the demands for increased production in the midst of massive SOP revisions was met with Movens's reply that his "hands were tied" due to Sun Pharma's control over Caraco operations;

c. Movens held and attended weekly, and eventually daily, meetings with Caraco employees to discuss quality issues, such as tablet variation, as corroborated by CW4, CW5, CW6 and CW8; and

d. the manufacturing and compliance problems at Caraco were rampant and pervasive, as corroborated by all of the confidential witnesses, to the point that, as stated by CW8, the problems were common knowledge and Movens must have known.

165. In short, Defendants continually told the FDA that Caraco would remedy its cGMP violations, and continually told or implied to the company's investors that the violations posed a minimal risk to the company since it was "substantially compliant." Both sets of representations were untrue.

166. Furthermore, Tammy Bitterman, a former Director of Human Resources and corporate secretary, compliance manager at Caraco, brought up FDA compliance issues directly with Defendant Movens. In her complaint captioned *Bitterman v. Caraco et al.*, Case No. 09-017205-CZ (Mich. Cir. Ct., Wayne County), filed on July 15, 2009 (the "*Bitterman* Complaint"), Ms. Bitterman alleges that she "learned that the plant was not meeting FDA standards concerning cleanliness of machines used for the production of pharmaceuticals." *Bitterman* Complaint at ¶10(e). Ms. Bitterman "reported these violations to upper management, ***specifically Movens***…." *Id.* at ¶14 (emphasis added). She further alleges that despite bringing "this concern to Movens [sic] attention, ***no action was taken to correct the situation***." *Id.* at ¶10(e) (emphasis added). Ms. Bitterman further alleges that she "learned that the machines were improperly measuring weight and that employees were being pressured to certify that the machine measured weight as well as size." *Id.* at ¶10(f).

167. Defendants were also on notice of the severity of the manufacturing issues at Caraco. Diane Kramer, in her complaint against Caraco entitled *Kramer v. Caraco Pharm. Laboratories, Ltd.* (Ill. Cir. Ct., Cook County) filed on May 27, 2009 (the "*Kramer* Complaint"), alleges that tablets of Caraco's Digoxin, USP, were defective and were part of the Digoxin voluntary recall described in an FDA press release dated March 31, 2009. *E.g. Kramer* Complaint at ¶¶31, 46, 47. She further alleges that her husband's death resulting from cardiac arrhythmia was caused by his consumption of Caraco's Digoxin tablets which were improperly manufactured and contained ***lethal*** doses of the active ingredient. *E.g., id.* at ¶¶1, 13, 14. Indeed, in its responsive pleading (upon removal of the action to federal court), Caraco admitted that "digoxin toxicity can present a risk to human health." Caraco's Answer at p. 9, Docket Item 10, Case No. 09-cv-3566 (N.D. Ill.; filed June 22, 2009).

168. Even after years of complaints and FDA observations about potentially dangerous variations in tablet sizes, Caraco and the Individual Defendants still failed to take steps to update and correct equipment and operating procedures to eliminate these variations. Defendants were on notice of numerous instances of tablet defects as listed in the Form FDA 483 issued to Caraco on May 12, 2009, particularly thin and thick tablets, in sorted and unsorted lots of drugs manufactured by Caraco, after process controls and compression related issued were noted by the FDA inspectors, including:

a. Digoxin 0.125 mg. tablets, USP lot 81404, was compressed between September 19 - 22, 2008, and noted for thick and soft tablets.

b. Digoxin 0.125 mg. tablets, USP lot 81401A, was compressed between June 14 – 20, 2008, and noted for thick and thin tablets during packaging.

c. Clonazepam 0.5 mg tablets, USP lot 81529A, was compressed between July 17 – 21, 2008, and noted for thin, soft, broken and imperfect tablets following the observation of these defects during packaging.

d. Clonazepam 0.5 mg tablets, USP lot 81534A, was sorted under two Special Processing Operation orders ("SPO") dated August 19, 2008, and November 11, 2008, following the observation of thin tablets during packaging.

e. Clonazepam 0.5 mg tablets, USP lot 81597A, was sorted under a Special Processing Operation order dated September 4, 2008, following the observation of thin tablets during packaging.

f. Clonazepam 0.5 mg tablets, USP lot 81532, was sorted under a Special Processing Operation order dated August 8, 2008, following the observation of thin tablets during packaging.

g. Metoprolol Tartrate 50 mg Tablets, USP lot 80345, was compressed between March 12 – 14, 2008 and noted for thin and soft tablets.

h. Metoprolol Tartrate 50 mg tablets, USP lot 82496, was sorted under two Special Processing Operation orders dated November 10, 2008, and November 18, 2008, following the observation of broken and thick tablets, as well as black spots, during compression and packaging.

i. Metoprolol Tartrate 50 mg tablets, USP lot 81786, was sorted under Special Processing Order dated August 20, 2008, following observation of soft tablets and imperfect appearance during packaging.

j. Metoprolol 50 mg tablets, USP lot 81102A, was sorted under Special Processing Order dated June 18, 2008, following observation of thick tablets during packaging.

k. Metoprolol 25 mg. tablets, USP lot 80667A, was sorted under Special Processing Order dated May 14, 2008, following observation of thick tablets during packaging.

l. Mirtazapine 30 mg tablets, USP lot 81126, was compressed beginning June 2 – 4, 2008, and noted for tablets with imperfect appearance.

m. Metoprolol Tartrate 50 mg. tablets, USP lot 80959, was compressed April 23 – 30, 2008, and received a complaint on September 3, 2008, for tablet size variations after compression.

n. Metoprolol Tartrate 25 mg. tablets, USP lot 81739A, was compressed August 26 – 28, 2008, and received a complaint on January 29, 2009, for tablet size variations after compression.

o. Metoprolol Tartrate 50 mg. round tablets, USP lot 82036A, was compressed between September 8-9, 2008, and received a complaint on January 28, 2009,for tablet size variation (thick) after compression.

p. Metoprolol Tartrate 25 mg tablets, USP lot 80658A, was compressed between April 11 – 14, 2008, and received a complaint on June 16, 2-0008 for tablet size variation (thick) after compression.

q. Metoprolol Tartrate 25 mg tablets, USP lot 82695A, was compressed between December 26-30, 2008, and received a complaint on March 12, 2009 for tablet size variation (thick) after compression.

r. Digoxin 0.125 mg. tablets, USP lot 81020A, was compressed on May 24 to June 2, 2008, and received a complaint on November 10, 2008, for tablet size variation (thick) after compression.

s. Digoxin 0.125 mg. tablets, USP lot 80771A, was compressed on May 1 – 6, 2008,received a complaint on July 2, 2008, for tablet size variation (thick) after compression.

169. Furthermore, Defendants were on notice of serious manufacturing problems, as numerous complaints flooded the Company regarding their manufactured drugs. There were numerous instances of Adverse Drug Event and/or complaints from consumers or health care professionals listed in the Form FDA 483 issued May 12, 2009, which were forwarded to Caraco, regarding tablet size variation and not thoroughly investigated, including:

a. Complaint 08-176 was received on or about December 4, 2008 regarding size and appearance variation in Digoxin 0.125 mg. tablets, USP lot 81404, but Caraco failed to follow-up the complaint despite finding 58 additional tablets with size variations in the retained samples taken from the same lot. The complaint was closed on January 15, 2009 without further action.

b. ADE 08-184 was received on or about November 10, 2008 regarding the same lot of Digoxin and involved hospitalization. Quality Control testing revealed variations from the labeled claim of 0.125 mg. nevertheless Caraco closed the

investigation on January 23, 2009 without performing a health hazard evaluation of the effect of consuming tablets with these variations.

c. ADE 08-101 was received on or about July 1, 2008 from a patient who experienced increased seizures, lips tingling, light-headedness and difficulty concentrating after taking Digoxin 0.125 mg. tablets, USP lot 80771A manufactured by Caraco for 2-3 weeks. An internal investigation confirmed that the sample tablets were out of tolerance for high weight but no action was taken as a result and the file was closed on September 4, 2008.

d. Complaint 08-149 was received on or about September 30, 2008 for Clonazepam 0.5 mg tablets, lot 81529A, due to variations in tablet size. Caraco evaluated retained samples and noted further examples of out of tolerance results for low weight and thickness. Caraco nevertheless closed the file without taking further action on November 10, 2008.

e. Complaint 08-095 was received on or about July 2, 2008 for oversized Mirtazapine 30 mg. tablets, USP lot 72694A. The complaint noted that "5 tablets in the bottle were larger and they jammed the equipment." Caraco evaluated the retained sample and noted 3 additional units out of tolerance for weight. Nevertheless, the file was closed without taking further action.

f. Clozapine tablets 100 mg tablets, USP lot 80849, were the subject of three complaints for broken tablets in June and July of 2008. Caraco evaluated the retained sample and discovered other tablet variations and evidence of excessive drying of the batch due to a power failure. Nevertheless, Caraco's

written investigation did not further address the excessive drying or further analyze the retained samples.

g. Complaint 08-083 was received on or about June 16 regarding oversized tablets from Metoprolol Tartrate 0.25 mg. tablets from USP lot 80658A. This was the 11th or 14 events associated with a particular tablet press. Caraco evaluated the retained samples and found tablets that exceeded Caraco's weight and thickness tolerances by a significant amount. Nevertheless, Caraco's record did not include the findings of any investigation or evidence of any follow-up.

h. Complaint 08-169 was received on or about November 11, 2008 for Metoprolol Tartrate 50 mg. tablets, USP lot 81785A, regarding oversized tablets. This complaint was the 5th complaint related to Metoprolol, the 15th overall complaint and the 8th incident for a particular tablet press related to tablet size received in 2008. Caraco received a complaint tablet outside of Caraco's tolerance range for thickness. Nevertheless, Caraco's records did not include the findings of any investigation or evidence of any follow-up.

i. Complaint 09-006 was received on or about January 28, 2009 regarding oversized Metoprolol Tartrate tablets from USP lot 81739A. This was the 12th of 14 events associated with the same tablet press. Caraco's records indicated problems with the beginning and middle of the tablet run and the complaint sample weighed "well in excess" or Caraco's upper tolerance for

weight. Nevertheless, Caraco's records did not include the findings of any investigation or evidence of any follow-up.

170. Moreover, the Individual Defendants signed Sarbanes-Oxley Certifications for the SEC filings during the class period. In doing so, they assumed responsibility for the completeness and accuracy of the filings – despite the fact that the filings failed to account for the pervasive and consistent cGMP violations and related problems.

XV. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

171. The market for Caraco's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Caraco's securities traded at artificially inflated prices during the Class Period. On May 30, 2008 the price of the Company's common stock closed at a Class Period high of $17.22 per share. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Caraco's securities and market information relating to Caraco, and have been damaged thereby.

172. During the Class Period, the artificial inflation of Caraco's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Caraco's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Caraco and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the

Company stock. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

173. At all relevant times, the market for Caraco's securities was an efficient market for the following reasons, among others:

(a) Caraco stock met the requirements for listing, and was listed and actively traded on the AMEX, a highly efficient and automated market;

(b) As a regulated issuer, Caraco filed periodic public reports with the SEC and the AMEX;

(c) Caraco regularly communicated with public investors *via* established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press, communications through its regularly maintained website with specific gateways for investors and other similar reporting services; and

(d) Caraco was followed by securities analysts employed by brokerage firms who wrote reports about Sun Pharma and the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

174. As a result of the foregoing, the market for Caraco's securities promptly digested current information regarding Caraco from all publicly available sources and reflected such information in Caraco's stock price. Under these circumstances, all purchasers of Caraco's

securities during the Class Period suffered similar injury through their purchase of Caraco's securities at artificially inflated prices and a presumption of reliance applies.

XVI. NO SAFE HARBOR

175. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Caraco who knew that the statement was false when made.

XVII. FIRST CLAIM

Violation of Section 10(b) of
The Exchange Act and Rule 10b-5
Promulgated Thereunder Against All Defendants

176. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

177. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (ii) cause Plaintiffs and other members of the Class to purchase Caraco's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

178. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Caraco's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

179. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Caraco's financial well-being and prospects, as specified herein.

180. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Caraco's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state

material facts necessary in order to make the statements made about Caraco and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

181. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

182. The defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Caraco's financial well-being and prospects from the

investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

183. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Caraco's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Caraco's securities during the Class Period at artificially high prices and were damaged thereby.

184. At the time of said misrepresentations and/or omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Caraco was experiencing, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Caraco securities,

or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

185. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

186. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

XVIII. SECOND CLAIM

Violation of Section 20(a) of The Exchange Act Against Sun Pharma and the Individual Defendants

187. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

188. Sun Pharma and the Individual Defendants acted as controlling persons of Caraco within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Sun Pharma and the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Sun Pharma and the Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs

to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

189. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same. Furthermore, Sun Pharma installed its own officers and/or directors on Caraco's board of directors and caused its own employees to supervise, manage and/or directly assume the day-to-day operations of the Company. Thus, Sun Pharma and the Individual Defendants were culpable participants in the fraud alleged herein.

190. As set forth above, Caraco and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, Sun Pharma and the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

XIX. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

DATED: February 11, 2010

THE MILLER LAW FIRM, P.C.

By: /s/ E. Powell Miller
E. Powell Miller (P39487)
Jayson E. Blake (P56128)
Christopher D. Kaye (P61918)
950 West University Drive, Suite 300
Rochester, Michigan 48307
Telephone: (248) 841-2200
Facsimile: (248) 652-2852

GLANCY BINKOW & GOLDBERG LLP
Lionel Z. Glancy
Peter A. Binkow
Michael Goldberg
1801 Avenue of the Stars, Suite 311
Los Angeles, California 90067
Telephone: (310) 201-9150
Facsimile: (310) 201-9160

Co-Lead Counsel for Plaintiffs

KENDALL LAW GROUP LLP
Joe Kendall
Hamilton Lindley
3232 McKinney, Suite 700
Dallas, TX 75204
Telephone: (214) 744-3000
Facsimile: (214) 744-3015

LAW OFFICES OF HOWARD G. SMITH
Howard G. Smith
3070 Bristol Pike, Suite 112
Bensalem, PA 19020
Telephone: (215) 638-4847
Facsimile: (215) 638-4867

Attorneys for Plaintiffs